**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF NEW YORK**

INTERNATIONAL UNION OF PAINTERS AND ALLIED TRADES 1974

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; RHODES TECHNOLOGIES; RHODES TECHNOLOGIES, INC.; RHODES PHARMACEUTICALS, L.P.; RHODES PHARMACEUTICALS INC.; THE P.F. LABORATORIES, INC.; RICHARD S. SACKLER; JONATHAN D. SACKLER; MORTIMER D.A. SACKLER; KATHE A. SACKLER; ILENE SACKLER LEFCOURT; BEVERLY SACKLER; THERESA SACKLER; DAVID A. SACKLER; TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY; STUART D. BAKER; ALLERGAN PLC f/k/a ACTAVIS PLC; CEPHALON, INC.; TEVA PHARMACEUTICALS USA, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; PAR PHARMACEUTICAL, INC.; INSYS THERAPEUTICS, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; SPECGX LLC; CARDINAL HEALTH, INC.; ANDA, INC.; MCKESSON CORPORATION; AMERISOURCEBERGEN DRUG CORPORATION; CVS HEALTH CORPORATION; THE KROGER CO.;

**COMPLAINT**
Case No.

**Jury Trial Demanded**

RITE AID OF MARYLAND, INC., dba RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER, INC.; RITE AID CORP.; WALGREENS BOOTS ALLIANCE, INC.; WALGREEN EASTERN CO., INC; WALGREEN, CO.; WAL-MART INC., f/k/a WAL-MART STORES, INC.; HD SMITH WHOLESALE DRUG COMPANY; and MIAMI-LUKEN, INC.

Defendants

## COMPLAINT

The Plaintiff, International Union of Painters and Allied Trades 1974 ("IUPAT")by and through its undersigned counsel, brings this Complaint against Defendants:

### INTRODUCTION

1. This case arises from the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids.[1]

2. The opioid crisis arose from pharmaceutical manufacturers' deliberately deceptive marketing strategy to expand opioid use, together with pharmaceutical distributors' equally deliberate efforts to evade restrictions on opioid distribution. Manufacturers and distributors alike acted without regard for the lives that would be trammeled in pursuit of profit.

3. Since the push to expand prescription opioid use began in the late 1990s, the death toll has steadily climbed, with no sign of slowing. The number of opioid overdoses in the United States rose from 8,000 in 1999 to over 20,000 in 2009, and over 33,000 in 2015. In the twelve months that ended in September 2017, opioid overdoses claimed 45,000 lives.

[1] Unless otherwise indicated, as used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

4. From 1999 through 2016, overdoses killed more than 350,000 Americans. Over 200,000 of them—more than were killed in the Vietnam War—died from opioids prescribed by doctors to treat pain. These opioids include brand-name prescription medications such as OxyContin, Opana ER, Vicodin, Subsys, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl.

5. Most of the overdoses from non-prescription opioids are also directly related to prescription pills. Many opioid users, having become addicted to but no longer able to obtain prescription opioids, have turned to heroin. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription opioids—which, at the molecular level and in their effect, closely resemble heroin. In fact, people who are addicted to prescription opioids are 40 times more likely to become addicted to heroin, and the Centers for Disease Control and Prevention ("CDC") identifies addiction to prescription opioids as the strongest risk factor for heroin addiction.

6. As a result, in part, of the proliferation of opioid pharmaceuticals between the late 1990s and 2015, the life expectancy for Americans decreased for the first time in recorded history. Drug overdoses are now the leading cause of death for Americans under 50.

7. In the words of Robert Anderson, who oversees death statistics at the CDC, "I don't think we've ever seen anything like this. Certainly not in modern times."

8. On October 27, 2017, the President declared the opioid epidemic a public health emergency.

9. This suit takes aim at the two primary causes of the opioid crisis: (a) a marketing scheme involving the false and deceptive marketing of prescription opioids, which was designed

to dramatically increase the demand for and sale of opioids and opioid prescriptions; and (b) a supply chain scheme, pursuant to which the various entities in the supply chain failed to design and operate systems to identify suspicious orders of prescription opioids, maintain effective controls against diversion, and halt suspicious orders when they were identified, thereby contributing to the oversupply of such drugs and fueling an illegal secondary market.

10. On the marketing side, the crisis was precipitated by the defendants who manufacture, sell, and market prescription opioid painkillers (defined below as "Manufacturing Defendants"). Through a massive marketing campaign premised on false and incomplete information, the Manufacturing Defendants engineered a dramatic shift in how and when opioids are prescribed by the medical community and used by patients. The Manufacturing Defendants relentlessly and methodically, but untruthfully, asserted that the risk of addiction was low when opioids were used to treat chronic pain, and overstated the benefits and trivialized the risk of the long-term use of opioids.

11. The Manufacturing Defendants' goal was simple: to dramatically increase sales by convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer or short-term post-operative pain, but also for common chronic pains, such as back pain and arthritis. They did this even though they knew that opioids were addictive and subject to abuse, and that their other claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

12. The Manufacturing Defendants' push to increase opioid sales worked. Through their publications and websites, endless stream of sales representatives, "education" programs, and other means, Manufacturing Defendants dramatically increased their sales of prescription opioids and reaped billions of dollars of profit as a result. Since 1999, the amount of prescription opioids

sold in the U.S. nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month.

13. Meanwhile, the Defendants made blockbuster profits. In 2012 alone, opioids generated $8 billion in revenue for drug companies. By 2015, sales of opioids grew to approximately $9.6 billion.

14. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, pharmacies, the Sackler family, and other related entities ("Defendants") who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls. These defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

15. From the day they made the pills to the day those pills were consumed in our community, Manufacturing Defendants had control over the information regarding addiction they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring doctors into prescribing their products by arguing, among other things, that no one should be in pain, Manufacturing Defendants created a population of addicted patients who sought opioids at never-before-seen rates. The scheme worked, and through it the Manufacturing Defendants caused their profits to soar as more and more people became dependent on opioids. Today, as many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in a

primary care setting struggles with addiction. And as of 2017, overdose death rates involving prescription opioids were five times higher than they were in 1999.

16. As millions of people became addicted to opioids, "pill mills," self-styled as "pain clinics," sprouted nationwide and rogue prescribers stepped in to supply prescriptions for non-medical use. These pill mills, typically under the auspices of licensed medical professionals, issue high volumes of opioid prescriptions under the guise of medical treatment. Prescription opioid pill mills and rogue prescribers cannot channel opioids for illicit use without the negligence, willful blindness, or knowing support of those in the supply chain.

17. As a direct and foreseeable result of Defendants' conduct, cities and counties across the nation, including Plaintiff, are now swept up in what the CDC has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis." The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids.

18. Thus, rather than compassionately helping patients in pain, this explosion in opioid use—and Defendants' enrichment—has come at the expense of patients and Plaintiff and has caused ongoing harm and damages to Plaintiff. As the CDC director concluded in 2014: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."

19. Defendants' conduct has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin. The costs are borne directly by Plaintiff and other governmental and non-governmental entities. These necessary and costly responses to the opioid crisis include, but are

not limited to, increased healthcare costs, the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing of children in foster care.

20. The burdens imposed on Plaintiff are not the normal or typical burdens of providing services to its members. Rather, these are extraordinary costs and losses that are directly caused by Defendants' illegal actions. Defendants' conduct has created a public nuisance and a blight. Governmental and non-governmental entities, and the services they provide their citizens, have been strained to the breaking point by this public health crisis.

21. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis.

22. Within the next hour, six Americans will die from opioid overdoses; two babies will be born dependent on opioids and begin to go through withdrawal; and drug manufacturers will earn over $2.7 million from the sale of opioids.

23. Plaintiff has filed this suit to bring the devastating march of this epidemic to a halt and to hold Defendants responsible for the harm for which they are to blame.

## JURISDICTION AND VENUE

24. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, et seq. ("RICO"). This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

25. This Court also has jurisdiction over this action in accordance with 28 U.S.C. § 1332(a), because the Plaintiff is a "citizen" of the State of New York and, upon information and

belief, the named Defendants are citizens of states other than New York, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

26. This Court has personal jurisdiction over Defendants because they conduct business in New York, purposefully direct or directed their actions toward New York, consented to be sued in New York by registering an agent for service of process, consensually submitted to the jurisdiction of New York when obtaining a manufacturer or distributor license, and have the requisite minimum contacts with New York necessary to constitutionally permit the Court to exercise jurisdiction.

27. This Court also has personal jurisdiction over all of the Defendants under 18 U.S.C. § 1965(b). This Court may exercise nation-wide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. See, e.g., Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc., 23 F. Supp. 2d 796 (1998) (citing LaSalle National Bank v. Arroyo Office Plaza, Ltd., 1988 WL 23824, *3 (N.D. Ill. Mar 10, 1988)); Butcher's Union Local No. 498 v. SDC Invest., Inc., 788 F.2d 535, 539 (9th Cir. 1986).

28. Venue is proper in the Eastern District of New York to 28 U.S.C. § 1391 and 18 U.S.C. §1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S.C. §§ 1391(b); 18 U.S.C. §1965(a).

# PARTIES

## I. PLAINTIFF

29. Plaintiff is organized and exists under the laws of the State of New York. Plaintiff IUPAT represents over 140,000 men and women in the United States and Canada. IUPAT local 1974 represents over 1100 construction members working in the finishing trades as painters, drywall finishers, wallcoverers, glaziers, glass workers, floor covering installers, sign makers, display workers, convention and show decorators, *inter alia*., their dependents and retirees. Plaintiff funds its own health insurance plan for the benefits of those participants, through which it pays part or all of its beneficiaries' health care costs, including the cost of prescription drugs, including opioids.

## II. DEFENDANTS

### A. Manufacturing Defendants

30. As used herein, the term "Manufacturing Defendants" includes the Defendants identified in this Section II(A).

31. At all relevant times, Manufacturing Defendants have manufactured, packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. In addition, the Manufacturing Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

#### *1. Purdue*

32. Defendant Purdue Pharma L.P. ("PPLP") is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

33. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut. It is the general partner of PPLP.

34. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut.

35. Defendant Rhodes Technologies ("Rhodes Tech") is a Delaware general partnership formed on April 12, 2005 with its principal place of business in Coventry, R.I.

36. Defendant Rhodes Technologies Inc. ("Rhodes Tech Inc.") is a Delaware corporation formed January 28, 1999 with its principal place of business in Coventry, R.I. Rhodes Tech Inc. is a general partner of Rhodes Tech.

37. Defendant Rhodes Pharmaceuticals L.P. ("Rhodes Pharma") is a Delaware limited partnership formed November 9, 2007 with its principal place of business in Coventry, R.I.

38. Defendant Rhodes Pharmaceuticals Inc. ("Rhodes Pharma Inc.") is a New York corporation formed on November 9, 2007. Rhodes Pharma Inc. is a general partner of Rhodes Pharma.

39. Defendant The P.F. Laboratories, Inc. ("PF Labs") is a New Jersey corporation with its principal place of business located in Totowa, New Jersey.

40. PPLP, PPI, PFC, Rhodes Tech, Rhodes Tech Inc., Rhodes Pharma, Rhodes Pharma Inc., and PF Labs are collectively referred to herein as "Purdue."

41. At all relevant times, Purdue has been beneficially owned, managed, and controlled by the families of Mortimer Sackler and Raymond Sackler, both of whom are now deceased.

42. Defendant Richard S. Sackler is a natural person residing in Travis County, Texas. He is a son of Raymond Sackler and, beginning in the 1990's, served as a member of the board of directors of Purdue and Purdue-related entities.

43. Defendant Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut. He is a son of Raymond Sackler and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

44. Defendant Mortimer D.A. Sackler is a natural person residing in New York County, New York. He is the son of Mortimer Sackler and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

45. Defendant Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

46. Defendant Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

47. Defendant Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Raymond Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

48. Defendant Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

49. Defendant David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and the grandson of Raymond Sackler) and has served as a member of the board of directors of Purdue and Purdue-related entities since 2012.

50. Defendant Trust for the Benefit of Members of the Raymond Sackler Family (the "Raymond Sackler Trust") is a trust of which Defendants Beverly Sackler, Richard S. Sackler, and/or Jonathan D. Sackler are trustees. It is the 50% direct or indirect beneficial owner of Purdue and the Purdue-related entities and the recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

51. Defendant Stuart D. Baker is a natural person residing in Suffolk County, New York. He has served as a senior executive of, and/or counsel to, Purdue, Purdue-related entities, and members of the Sackler families since the 1990s.

52. Purdue engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in the State of New York including among Plaintiff's members in New York and surrounding areas (collectively, "Plaintiff's Community"), including branded and generic versions of the following:

**Purdue Opioids**

| **Drug Name** | **Chemical Name** | **Schedule**[2] |
|---|---|---|
| OxyContin | Oxycodone hydrochloride extended release | Schedule II |

[2] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

| | | |
|---|---|---|
| MS Contin | Morphine sulfate extended release | Schedule II |
| Dilaudid | Hydromorphone hydrochloride | Schedule II |
| Dilaudid-HP | Hydromorphone hydrochloride | Schedule II |
| Butrans | Byprenorpine | Schedule III |
| Hysingla ER | Hydrocodone bitrate | Schedule II |
| Targiniq ER | Oxycodone hydrochloride and naloxone hydrochloride | Schedule II |

53. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $3.1 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (i.e., painkillers). OxyContin went from a mere $49 million in its first full year on the market to $1.6 billion in 2002.

54. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the Unites States $635 million – at the time, one of the largest settlements with a drug company for marketing misconduct. At the same time, Purdue executive officers Michael Friedman (the CEO), Howard Udell (Vice President and General Counsel), and Paul Goldenheim (Chief Medical Officer) pleaded guilty to criminal charges that they let Purdue deceive doctors and patients about its opioids. Pursuant to its settlement, Purdue operated under a Corporate Integrity Agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services, which required the company and its officers and directors, *inter alia*, to ensure that its marketing was fair and accurate, and to monitor and report on its compliance with the Agreement. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, despite the criminal convictions

and the fine, Purdue continued to deceptively market and sell billions of dollars of opioids each year.

55. Purdue made thousands of payments to physicians nationwide, including in New York, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

56. Each of Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler, Raymond Sackler Trust, and Stuart D. Baker (collectively "Purdue-Related Additional Defendants") knowingly directed, aided, abetted, participated in, and benefitted from the wrongdoing of Purdue alleged herein.

### *2. Actavis*

57. Defendant Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in or about March 2015, and the combined company changed its name to Allergan PLC in or about March 2015. Defendant Actavis, Inc. was acquired by Watson Pharmaceuticals, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis PLC in October 2013. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Defendant Actavis Pharma, Inc. is registered to do business with the Ohio Secretary of State as a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants and entities is owned by Defendant Allergan PLC, which uses

them to market and sell its drugs in the United States. Collectively, these defendants and entities are referred to as "Actavis."

58. Actavis manufactures or has manufactured the following drugs as well as generic versions of Kadian, Duragesic, and Opana in the United States:

**Actavis Opioids**

| **Product Name** | **Chemical Name** | **Schedule** |
|---|---|---|
| Kadian | Morphine sulfate, extended release | Schedule II |
| Norco | Hydrocodone bitartate and acetaminophen | Schedule II |

59. Actavis made thousands of payments to physicians nationwide, including in New York, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

***3. Cephalon***

60. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Whales, Pennsylvania. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009. Teva USA is a wholly-owned subsidiary of Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation (collectively "Teva").

61. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

62. Teva USA and Cephalon, Inc. (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of opioids nationally and in New York, including the following:

**Cephalon Opioids**

| Drug Name | Chemical Name | Schedule |
|---|---|---|
| Actiq | Fentanyl citrate | Schedule II |
| Fentora | Fentanyl citrate | Schedule II |

63. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin beginning in 2005 nationally and in New York.

64. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in New York, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, many of whom were not oncologists and did not treat cancer pain, but in fact to deceptively promote and maximize the use of opioids.

***4. Janssen***

65. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

66. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of J&J. Janssen Pharmaceuticals was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

67. Defendant Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital.

68. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

69. Defendant Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

70. J&J, Janssen Pharmaceuticals, Noramco, OMP, and Janssen Pharmaceutica (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in New York. Among the drugs Janssen manufactures or manufactured are the following:

**Janssen Opioids**

| **Drug Name** | **Chemical Name** | **Schedule** |
|---|---|---|
| Duragesic | Fentanyl | Schedule II |
| Nucynta[3] | Tapentadol extended release | Schedule II |
| Nucynta ER | Tapentadol | Schedule II |

71. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

[3] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

72. Janssen, like many other companies, has a corporate code of conduct, which clarifies the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

73. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of Johnson & Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, and sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case.

74. J&J controls the sale and development of Janssen's drugs, J&J handles Jansen's dealings with the FDA concerning Janssen's drugs, and Janssen's profits inure to J&J's benefit.

75. Janssen made thousands of payments to physicians nationwide, including in New York, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

### *5. Endo*

76. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

77. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly-owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

78. Defendant Par Pharmaceutical, Inc. is a New York corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Defendant Par Pharmaceutical Companies, Inc., a Delaware corporation with its principal place of business in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are referred to collectively herein as "Par Pharmaceutical."

79. EHS, EPI, and Par Pharmaceutical, and their DEA registrant subsidiaries and affiliates (collectively, "Endo"), manufacture, promote, distribute and sell opioids throughout the United States and in New York, including the following:

**Endo Opioids**

| Drug Name | Chemical Name | Schedule |
|---|---|---|
| Opana ER | Oxymorphone hydrochloride extended release | Schedule II |
| Opana | Oxymorphone hydrochloride | Schedule II |
| Percodan | Oxymorphone hydrochloride and aspirin | Schedule II |
| Percocet | Oxymorphone hydrochloride and acetaminophen | Schedule II |
| Generic | Oxycodone | Schedule II |
| Generic | Oxymorphone | Schedule II |
| Generic | Hydromorphone | Schedule II |

80. Endo made thousands of payments to physicians nationwide, including in New York, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

81. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012, accounting for over 10% of Endo's total revenue; Opana ER yielded revenue of $1.15 billion from 2010 to 2013. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

82. The Food and Drug Administration ("FDA") requested that Endo remove Opana ER from the market in June 2017. The FDA relied on post-marketing data in reaching its conclusion based on risk of abuse.

***6. Insys***

83. Insys Therapeutics, Inc. is a Delaware corporation with its principal place of business in Chandler, Arizona.

84. Insys is or has been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in New York. Among the drugs Insys manufactures or manufactured are the following:

**Insys Opioids**

| **Product Name** | **Chemical Name** | **Schedule** |
|---|---|---|
| Subsys | Fentanyl | Schedule II |

85. Insys made thousands of payments to physicians nationwide, including in New York, ostensibly for activities including participating on speakers' bureaus, providing consulting

services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

86. Insys's principal product and source of revenue is Subsys, a transmucosal immediate-release formulation (TIRF) of fentanyl, contained in a single-dose spray device intended for oral, under the tongue administration. Subsys was approved by the FDA solely for the treatment of breakthrough cancer pain.

87. In 2016, Insys made approximately $330 million in net revenue from Subsys. Insys promotes, sells, and distributes Subsys throughout the United States, and in New York.

88. Insys's founder and owner was recently arrested and charged, along with other Insys executives, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. Other Insys executives and managers were previously indicted.

***7. Mallinckrodt***

89. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June 2013. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri.

90. Defendant Mallinckrodt LLC is a Delaware corporation with its principal place of business in Hazelwood, Missouri.

91. Defendant SpecGx LLC is a Delaware limited liability company with its principal place of business in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc.

92. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates (together, "Mallinckrodt") manufacture, market, sell and distribute pharmaceutical drugs throughout the United States and in New York.

93. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States based on prescriptions.

94. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

95. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the DEA's entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

96. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors,

specialty pharmaceutical distributors, retail pharmacy chains, and pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

97. Among the drugs Mallinckrodt manufactures or has manufactured are the following:

**Mallinckrodt Opioids**

| **Product Name** | **Chemical Name** | **Schedule** |
|---|---|---|
| Exalgo | Hydromorphone hydrochloride, extended release | Schedule II |
| Roxicodone | Oxycodone hydrochloride | Schedule II |
| Xartemis XR | Oxycodone hydrochloride and acetaminophen | Schedule II |
| Methadose | Methadone hydrochloride | Schedule II |
| Generic | Morphine sulfate, extended release | Schedule II |
| Generic | Morphine sulfate oral solution | Schedule II |
| Generic | Fentanyl transdermal system | Schedule II |
| Generic | Oral transmucosal fentanyl citrate | Schedule II |
| Generic | Oxycodone and acetaminophen | Schedule II |
| Generic | Hydrocodone bitartrate and acetaminophen | Schedule II |
| Generic | Hydromorphone hydrochloride | Schedule II |
| Generic | Hydromorphone hydrochloride, extended release | Schedule II |
| Generic | Naltrexone hydrochloride | unscheduled |
| Generic | Oxymorphone hydrochloride | Schedule II |
| Generic | Methadone hydrochloride | Schedule II |
| Generic | Oxycodone hydrochloride | Schedule II |
| Generic | Buprenorphine and naloxone | Schedule III |

98. Mallinckrodt made thousands of payments to physicians nationwide, including in New York, ostensibly for activities including participating on speakers' bureaus, providing

consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

#### *8. "Manufacturing Defendants" Defined*

99. Collectively, Purdue, Purdue-Related Additional Defendants, Actavis, Cephalon, Janssen, Endo, Insys, and Mallinckrodt are referred to as "Manufacturing Defendants" or "Manufacturer Defendants."

### B. Distributor Defendants

100. As used herein, the term "Distributor Defendants" includes the Defendants identified in this Section II(B).

101. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is a substantial cause for the excessive volume of prescription opioids plaguing Plaintiff's Community and of the diversion of prescription opioids into Plaintiff's Community.

#### *1. Cardinal*

102. Cardinal Health, Inc. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio.

103. Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including in New York.

104. Cardinal describes itself as a "global, integrated health care services and products company," and it is the fifteenth largest company by revenue in the U.S., with annual revenue of $121 billion in 2016.

105. Cardinal has been licensed as a wholesale distributor of dangerous drugs in New York since 1990.

106. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

***2. Anda***

107. Defendant Anda, Inc. ("Anda"), is a Florida corporation with its principal office located in Olive Branch, Mississippi. Through its various DEA registrant subsidiaries and affiliated entities, Anda is the fourth largest distributor of generic pharmaceuticals in the United States. In October 2016, Defendant Teva USA acquired Anda for $500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in New York.

***3. McKesson***

108. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in San Francisco, California.

109. McKesson is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including New York.

110. In January 2017, McKesson paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan and Colorado.

The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [DEA] registered distributor."

### *4. AmerisourceBergen*

111. AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware Corporation with its principal place of business in Chesterbrook, Pennsylvania.

112. AmerisourceBergen distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including in New York.

113. AmerisourceBergen is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016.

114. AmerisourceBergen has been licensed as a wholesale distributor of dangerous drugs in New York since 1988.

### *5. CVS*

115. Defendant CVS Health Corporation ("CVS") is a Delaware corporation with its principal place of business in Rhode Island. CVS, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. CVS also operates retail stores which sell prescription medicines including opioids.

116. At all times relevant to this Complaint, CVS distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in New York.

### *6. Kroger*

117. Defendant The Kroger Co. ("Kroger) is an Ohio corporation with headquarters in Cincinnati, OH.

118. Kroger operates 2,268 pharmacies in the United States, including in New York.

119. At all times relevant to this Complaint, Kroger distributed prescription opioids throughout the United States, including in New York.

### *7. Rite-Aid*

120. Defendant Rite Aid of Maryland, Inc., dba Rite Aid Mid-Atlantic Customer Support Center, Inc., is a Maryland corporation with its principal office located in Camp Hill, Pennsylvania.

121. Defendant Rite Aid Corp. is a Delaware corporation with its principal offices located in Camp Hill, Pennsylvania. Together, Rite Aid of Maryland, Inc. and Rite Aid Corp. are referred to as "Rite Aid."

122. Rite Aid, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor.

123. Rite-Aid also operates retail stores, which sell prescription medicines, including opioids.

124. At all times relevant to this Complaint, Rite Aid, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in New York.

### *8. Walgreens*

125. Defendant Walgreens Boots Alliance, Inc., is a Delaware corporation with its principal place of business in Illinois.

126. Defendant Walgreen Eastern Co., Inc. is a subsidiary of Walgreens Boots Alliance, Inc. that is engaged in the business of distributing pharmaceuticals, including prescription opioids.

127. Defendant Walgreen, Co. is a subsidiary of Walgreens Boots Alliance that operates retail drug stores.

128. Together, Walgreens Boots Alliance, Inc., Walgreen Eastern Co., Inc. and Walgreen Co. are referred to as "Walgreens."

129. Walgreens, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walgreens distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in New York.

***9. Wal-Mart***

130. Defendant Wal-Mart Inc., formerly known as Wal-Mart Stores, Inc. ("Wal-Mart"), is a Delaware corporation with its principal place of business in Arkansas. Wal-Mart, through its various DEA registered affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in New York.

***10. H.D. Smith***

131. Defendant HD Smith Wholesale Drug Company ("H.D. Smith") is a Delaware corporation with its principal place of business in Springfield, Illinois. H.D. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic, and specialty pharmaceuticals. At all times relevant to this Complaint, H.D. Smith distributed prescription opioids throughout the United States, including in New York.

***11. Miami-Luken***

132. Defendant Miami-Luken, Inc. ("Miami-Luken") is an Ohio corporation with its headquarters and principal place of business in Springboro, Ohio. At all times relevant to this Complaint, Miami-Luken distributed prescription opioids throughout the United States, including in New York.

#### *12. "National Retail Pharmacies" Defined*

133. Collectively, Defendants CVS, Kroger, Rite Aid, Walgreens, and Wal-Mart are referred to as "National Retail Pharmacies."

#### *13. "Distributor Defendants" Defined*

134. Cardinal, McKesson, AmerisourceBergen, H.D. Smith, Miami-Luken, and the National Retail Pharmacies are collectively referred to as the "Distributor Defendants."

### C. Agency and Authority

135. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

### D. Affiliates of Named Defendants

136. Defendants include the above-referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution, sale, and/or dispensing of opioids.

## FACTS COMMON TO ALL CLAIMS

### I. OPIOIDS AND THEIR EFFECTS

137. The term "opioid" refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from the opium poppy. Generally used to treat pain, opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression.

138. The medicinal properties of opioids have been recognized for millennia—as well as their potential for abuse and addiction. The opium poppy contains various opium alkaloids,

three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine. Early use of opium in Western medicine was with a tincture of opium and alcohol called laudanum, which contains all of the opium alkaloids and is still available by prescription today. Chemists first isolated the morphine and codeine alkaloids in the early 1800s.

139. In 1827, the pharmaceutical company Merck began large-scale production and commercial marketing of morphine. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to treat the wounded, and many veterans were left with morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms. The nation's first Opium Commissioner, Hamilton Wright, remarked in 1911, "The habit has this nation in its grip to an astonishing extent. Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who prey upon their fellows … it has become one of the most fertile causes of unhappiness and sin in the United States."

140. Pharmaceutical companies tried to develop substitutes for opium and morphine that would provide the same analgesic effects without the addictive properties. In 1898, Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of morphine) under the trade name "Heroin." Bayer advertised heroin as a non-addictive cough and cold remedy suitable for children, but as its addictive nature became clear, heroin distribution in the U.S. was limited to prescription only in 1914 and then banned altogether a decade later.

141. Although heroin and opium became classified as illicit drugs, there is little difference between them and prescription opioids. Prescription opioids are synthesized from the

same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

142. Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970.

143. Throughout the twentieth century, pharmaceutical companies continued to develop prescription opioids like Percodan, Percocet, and Vicodin, but these opioids were generally produced in combination with other drugs, with relatively low opioid content.

144. In contrast, OxyContin, the product whose launch in 1996 ushered in the modern opioid epidemic, is pure oxycodone. Purdue initially made it available in the following strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. The weakest OxyContin delivers as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times that.

145. Medical professionals describe the strength of various opioids in terms of morphine milligram equivalents ("MME"). According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day.

146. Different opioids provide varying levels of MMEs. For example, just 33 mg of oxycodone provides 50 MME. Thus, at OxyContin's twice-daily dosing, the 50 MME/day threshold is nearly reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which Purdue took off the market in 2001, delivered 240 MME.

147. The wide variation in the MME strength of prescription opioids renders misleading any effort to capture "market share" by the number of pills or prescriptions attributed to Purdue or

other manufacturers. Purdue, in particular, focuses its business on branded, highly potent pills, causing it to be responsible for a significant percentage of the total amount of MME in circulation, even though it currently claims to have a small percentage of the market share in terms of pills or prescriptions.

148. Fentanyl is a synthetic opioid that is 100 times stronger than morphine and 50 times stronger than heroin. First developed in 1959, fentanyl is showing up more and more often in the market for opioids created by Manufacturing Defendants' promotion, with particularly lethal consequences.

149. The effects of opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours. Still other short-term opioids, such as Insys's Subsys, are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The Manufacturing Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or "breakthrough" pain.

150. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the

"high." However, opioids depress respiration, and at very high doses can, and often do, arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

151. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

152. As a leading pain specialist doctor put it, the widespread, long-term use of opioids "was a *de facto* experiment on the population of the United States. It wasn't randomized, it wasn't controlled, and no data was collected until they started gathering death statistics."

## II. THE RESURGENCE OF OPIOID USE IN THE UNITED STATES

### A. The Sackler Family Integrated Advertising and Medicine

153. Given the history of opioid abuse in the U.S. and the medical profession's resulting wariness, the commercial success of the Manufacturer Defendants' prescription opioids would not have been possible without a fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use.

154. As it turned out, Purdue was uniquely positioned to execute just such a maneuver, thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of Purdue and one of the wealthiest families in America, with an estimated net worth of $13 billion as of 2016. All of Purdue's profits go to Sackler family trusts and entities and, through them, to members of the Sackler families.

155. Arthur Sackler was both a psychiatrist and a marketing executive, and, by many accounts, a brilliant and driven man. He pursued two careers simultaneously, as a psychiatrist at

Creedmoor State Hospital in New York and the president of an advertising agency called William Douglas McAdams. He pioneered both print advertising in medical journals and promotion through physician "education" in the form of seminars and continuing medical education ("CME") courses. He also understood the persuasive power of recommendations from fellow physicians, and did not hesitate to manipulate information when necessary. For example, one promotional brochure produced by his firm for Pfizer showed business cards of physicians from various cities as if they were testimonials for the drug, but when a journalist tried to contact these doctors, he discovered that they did not exist.

156. Arthur Sackler revolutionized medical marketing in the 1950's and 60's by creating the very marketing ploys his family later used to perpetuate the massive fraud alleged in this action. In striving to make Pfizer (with its blockbuster drug, Valium) a household name among physicians, Arthur Sackler recognized that "selling new drugs requires a seduction of not just the patient but the doctor who writes the prescription," and he maximized influence over physician prescribing by developing the following marketing ploys to disseminate pharmaceutical messaging under the guise of science and truth:

a. contacting prescribers directly with a variety of perks, benefits and even job offers;

b. publishing seemingly neutral articles in medical journals, citing scientific studies (frequently underwritten by the pharmaceutical companies whose products he was marketing);

c. marketing illnesses (i.e., lamenting and marketing the under treatment of purported illnesses and the corresponding under-utilization of drugs he was promoting);

d. paying prominent physicians to endorse his products; and

e. funding CMEs, controlling the messaging of key opinion leaders, and maximizing influence over physician prescribing practices.

157. In the 1960s Arthur Sackler made Valium into the first $100-million drug, so popular it became known as "Mother's Little Helper." His expertise as a psychiatrist was one of the keys to his success. When Arthur's client, Roche, developed Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for treatment of anxiety. So Arthur invented a condition he called "psychic tension"—essentially stress—and pitched Valium as the solution. The campaign, for which Arthur was compensated based on volume of pills sold, was a remarkable success.

158. Arthur Sackler created not only the advertising for his clients but also the vehicle to bring their advertisements to doctors—a biweekly newspaper called the *Medical Tribune*, which was distributed for free to doctors nationwide. Arthur also co-founded a company called IMS Health ("IMS") (which is now part of IQVIA), which monitors prescribing practices of every doctor in the U.S. and sells the data to pharmaceutical companies like Manufacturing Defendants, who utilize it to target and tailor their sales pitches to individual physicians.

159. In marketing tranquilizers Librium and Valium, Arthur Sackler broadened his customer base to potentially include everyone. For example, one campaign encouraged doctors to prescribe Valium to people with no psychiatric symptoms whatsoever, urging doctors to "consider the usefulness of Valium" in patients with ***no*** demonstrable pathology. Such marketing led one physician, writing in the journal *Psychosomatics* in 1965, to ask, "When do we *not* use this drug?'"

160. As the line between medical education and medical marketing became deliberately blurred, Valium became the pharmaceutical industry's first hundred-million-dollar, and then billion-dollar, drug. For his design and creation of these medical marketing strategies, he was posthumously inducted into the Medical Advertising Hall of Fame, but, as succinctly put by Allen Frances, the former chair of psychiatry at Duke University School of Medicine: "Most of the

questionable practices that propelled the pharmaceutical industry into the scourge it is today can be attributed to Arthur Sackler."

161. In other precursors of the current crisis, Arthur Sackler promoted these drugs despite the lack of any studies of their addictive potential. Additionally, he started *Medical Tribune*, despite concerns that a pharmaceutical advertiser should not be publishing a medical periodical directed at doctors. He paid Key Opinion Leaders ("KOLs"), including for example, Henry Welch (then chief of FDA's antibiotics division), almost $300,000 in exchange for his help in promoting pharmaceutical drugs. By the 1970's, doctors were prescribing more than 100 million tranquilizer prescriptions annually, creating what Sen. Edward Kennedy called "a nightmare of dependence and addiction."

**B. Purdue and the Development of OxyContin**

162. In 1952, Arthur Sackler and his two brothers Mortimer Sackler and Raymond Sackler—purchased what was then a small patent-medicine company called the Purdue Frederick Company ("PF Co.").

163. PF Co. had been formed in 1892 by Dr. John Purdue Gray and George Frederick Bingham and incorporated in New York on June 29, 1911.

164. After Arthur's death, Mortimer and Raymond bought out his share. Since that time, PF Co. and all Purdue-related companies have all been owned and controlled by the Raymond Sackler Family and the Mortimer Sackler Family.

165. PF Co. is no longer an active New York corporation, having been merged into Defendant PF Labs on May 7, 2004.

166. At all relevant times, PF Co. and PF Labs have been beneficially owned by the Sackler Families and controlled by them through Defendant Sackler Family members.

167. After the Sacklers acquired PF Co. in 1952, they sold products ranging from earwax remover to antiseptic, and it became a profitable business. As an advertising executive, Arthur Sackler was not involved, on paper at least, in running the family business, which would have been a conflict of interest. Raymond Sackler became Purdue's head executive, while Mortimer Sackler ran Purdue's UK affiliate.

168. Beginning in the 1980s PF Co. and its associated companies engaged in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling or distributing opioids throughout the United States.

169. In the 1980s, the Sacklers, through a UK company they owned, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. They marketed this extended-release morphine as MS Contin, and it quickly became their bestseller. As the patent expiration for MS Contin loomed, they searched for a drug to replace it. Around that time, Raymond's oldest son, Defendant Richard Sackler, who was also a trained physician, became more involved in the management of the family business. Richard had grand ambitions for the company. According to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I mean *really* big." Richard believed Purdue should develop another use for its "Contin" timed-release system.

170. OxyContin was created by PF Co., but responsibility for designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling, and distributing OxyContin and other opioid products was shared among PF Co., Purdue, PF Labs, and other Purdue-related companies.

171. At relevant times, OxyContin was manufactured by PF Labs.

172. In 1990, Purdue's vice president of clinical research, Robert Kaiko, sent a memo to Richard and other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, a relatively weak oxycodone-acetaminophen combination pill, or Percodan, where it was blended with aspirin. By contrast, the oxycodone pill developed by Purdue—OxyContin—was pure oxycodone in a time-release formula similar to MS Contin, and it was more potent than morphine. Purdue also decided to produce pills with as much as 160 milligrams of oxycodone, far in excess of any other prescription opioid.

173. MS Contin was not only approaching patent expiration but had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what's more, it was sometimes mistakenly called "oxycodeine," which also contributed to the perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this false perception to its advantage when it later pled guilty to criminal charges of "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps … that would affect the unique position that OxyContin'" held among physicians.

174. Even though oxycodone did not have the same stigma as morphine, in focus groups conducted before OxyContin's release, Purdue learned that doctors were concerned about the abuse potential of opioids. The focus group concluded that the perceived abuse potential of opioids was the "'biggest negative' that might prevent widespread use of the drug."

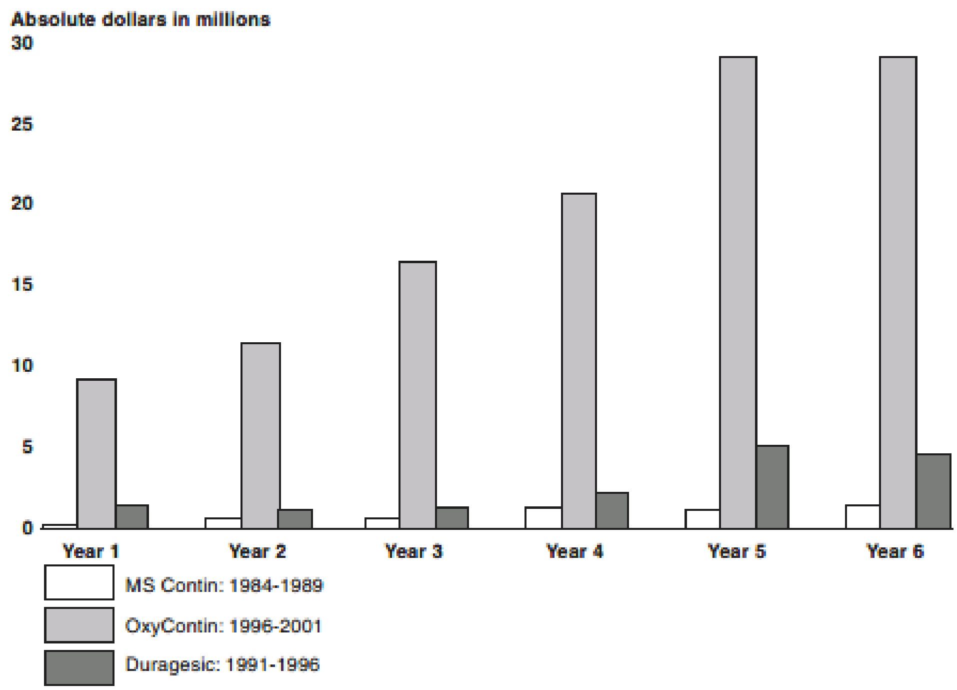
175. For Purdue and OxyContin to be "*really* big," Purdue needed to both distance its new product from the traditional view of narcotic addiction risk, and broaden the drug's uses

beyond cancer pain and hospice care. A marketing memo sent to Purdue's top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase. As described below, Purdue did not have any such evidence, but this did not stop Purdue from making that claim regardless.

176. Armed with this and other misrepresentations about the risks and benefits of its new drug, Purdue was able to open an enormous untapped market: patients with non-end-of-life, non-acute, everyday aches and pains. As Dr. David Haddox ("Dr. Haddox"), a Senior Medical Director at Purdue, declared, "[t]here are 50 million patients in this country who have chronic pain that's not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that."

177. In pursuit of those 50 million potential customers, Purdue poured resources into OxyContin's sales force and advertising, particularly to a far broader audience of primary care physicians who treated patients with chronic pain complaints. The graph below shows how promotional spending in the first six years following OxyContin's launch dwarfed Purdue's spending on MS Contin or Defendant Janssen's spending on its opioid product Duragesic:

**Figure 1: Promotional Spending for Three Opioid Analgesics in First 6 Years of Sales**




Source: DEA and IMS Health, Integrated Promotional Service Audit.

Note: Dollars are 2002 adjusted.

178. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners.

179. In the two decades following OxyContin's launch, Purdue continued to devote substantial resources to its promotional efforts. Nearly *half* of Purdue's operating expenses in 2015 went to sales and promotion, and more than 80% of its marketing budget of $241 million was spent on sending sales representatives to meet with prescribers.

180. Purdue has generated estimated sales of more than $35 billion from opioids since 1996, raking in more than $3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself

skilled at evading full responsibility and continuing to sell through the controversy. The company's annual opioid sales of $3 billion in 2015 represent a four-fold increase from its 2006 sales of $800 million.

181. One might imagine that Richard Sackler's ambitions have been realized. But in the best tradition of family patriarch Arthur Sackler, Purdue has its eyes on even greater profits. Under the name of Mundipharma, the Sacklers are looking to new markets for their opioids—employing the exact same playbook in South America, China, and India as they did in the United States.

182. In May 2017, a dozen members of Congress sent a letter to the World Health Organization, warning it of the deceptive practices Purdue is unleashing on the rest of the world through Mundipharma:

> We write to warn the international community of the deceptive and dangerous practices of Mundipharma International—an arm of Purdue Pharmaceuticals. The greed and recklessness of one company and its partners helped spark a public health crisis in the United States that will take generations to fully repair. We urge the World Health Organization (WHO) to do everything in its power to avoid allowing the same people to begin a worldwide opioid epidemic. Please learn from our experience and do not allow Mundipharma to carry on Purdue's deadly legacy on a global stage. . . .
>
> Internal documents revealed in court proceedings now tell us that since the early development of OxyContin, Purdue was aware of the high risk of addiction it carried. Combined with the misleading and aggressive marketing of the drug by its partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated American communities since the end of the 1990s. Today, Mundipharma is using many of the same deceptive and reckless practices to sell OxyContin abroad. . . .
>
> In response to the growing scrutiny and diminished U.S. sales, the Sacklers have simply moved on. On December 18, the Los Angeles Times published an extremely troubling report detailing how in spite of the scores of lawsuits against Purdue for its role in the U.S. opioid crisis, and tens of thousands of overdose deaths, Mundipharma now aggressively markets OxyContin internationally. In fact, Mundipharma uses many of the same tactics that caused the opioid epidemic to flourish in the U.S., though now in countries with far fewer resources to devote to the fallout.

183. Purdue's recent pivot to untapped markets—after extracting substantial profits from American communities and leaving local governments to address the devastating and still

growing damage the company caused—only serves to underscore that Purdue's actions have been knowing, intentional, and motivated by profits throughout this entire story.

### C. Other Manufacturer Defendants Leapt at the Opioid Opportunity

184. Purdue created a market for the use of opioids for a range of common aches and pains by misrepresenting the risks and benefits of its opioids, but it was not alone. The other Manufacturer Defendants—already manufacturers of prescription opioids—positioned themselves to take advantage of the opportunity Purdue created, developing both branded and generic opioids to compete with OxyContin, while, together with Purdue and each other, misrepresenting the safety and efficacy of their products. These misrepresentations are described in detail below.

185. Endo, which already sold Percocet and Percodan, was the first to submit an application for a generic extended-release oxycodone to compete with OxyContin. At the same time, Endo sought FDA approval for another potent opioid, immediate-release and extended-release oxymorphone, branded as Opana and Opana ER. Oxymorphone, like OxyContin's active ingredient oxycodone, is not a new drug; it was first synthesized in Germany in 1914 and sold in the U.S. by Endo beginning in 1959 under the trade name Numorphan. But Numorphan tablets proved highly susceptible to abuse. Called "blues" after the light blue color of the 10 mg pills, Numorphan provoked, according to some users, a more euphoric high than heroin. As the National Institute on Drug Abuse observed in its 1974 report, "Drugs and Addict Lifestyle," Numorphan was extremely popular among addicts for its quick and sustained effect. Endo withdrew oral Numorphan from the market in 1979.

186. Two decades later, however, as communities around the U.S. were first sounding the alarm about prescription opioids and Purdue executives were being called to testify before Congress about the risks of OxyContin, Endo essentially reached back into its inventory, dusted

off a product it had previously shelved after widespread abuse, and reintroduced it into the marketplace with a new trade name, Opana.

187. The clinical trials submitted with Endo's first application for approval of Opana were insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be revived with naloxone. Endo then submitted new "enriched enrollment" clinical trials, in which trial subjects who do not respond to the drug are excluded from the trial, and obtained approval. Endo began marketing Opana and Opana ER, an extended release formulation, in 2006.

188. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017, the FDA sought removal of Opana ER. In its press release, the FDA indicated that this is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse. On July 6, 2017, Endo agreed to withdraw Opana ER from the market.

189. Janssen, which already marketed the Duragesic (fentanyl) patch for severe pain, also joined Purdue in pursuit of the broader chronic pain market. It sought to expand the use of Duragesic through, for example, advertisements proclaiming, "It's not just for end stage cancer anymore!" This claim earned Janssen a warning letter from the FDA, for representing that Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence."

190. Janssen also developed a new opioid compound called tapentadol in 2009, marketed as Nucynta for the treatment of moderate to severe pain. Janssen launched the extended-release version, Nucynta ER, for treatment of chronic pain in 2011.

191. By adding additional opioids or expanding the use of their existing opioid products, the other Manufacturing Defendants took advantage of the market created by Purdue's aggressive

promotion of OxyContin and reaped enormous profits. For example, Opana ER alone generated more than $1 billion in revenue for Endo in 2010 and again in 2013. Janssen also passed the $1 billion mark in sales of Duragesic in 2009.

## III. Defendants' Conduct Created an Abatable Public Nuisance

192. Defendants' conduct created a public health crisis and a public nuisance.

193. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated by, *inter alia*, (a) educating prescribers (especially primary care physicians and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to patients who are already addicted to opioids; and (c) making naloxone widely available so that overdoses are less frequently fatal.

194. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they are uniquely well positioned to do so. The manufacturer of a drug has a duty to assure the safety and efficacy of the drug and the appropriateness of the drug's labeling, marketing, and promotion. All companies in the supply chain of a controlled substance have a duty to ensure that such drugs are only distributed and dispensed to appropriate patients and not diverted. These duties exist independent of any federal or state statute or regulation. As registered manufacturers and distributors of controlled substances, Defendants occupy a position of special trust and responsibility and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a first line of defense against the harm that opioids can cause.

## IV. The Manufacturer Defendants' Multi-Pronged Scheme to Change Prescriber Habits and Public Perception and Increase Demand for Opioids

195. In order to accomplish the fundamental shift in perception that was key to successfully marketing their opioids, the Manufacturer Defendants designed and implemented a sophisticated and deceptive marketing strategy. Lacking legitimate scientific research to support their claims, the Manufacturer Defendants turned to the marketing techniques first pioneered by Arthur Sackler to create a series of misperceptions in the medical community and ultimately reverse the long-settled understanding of the relative risks and benefits of opioids.

196. The Manufacturing Defendants promoted, and profited from, their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Manufacturing Defendants of these risks. The Manufacturing Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC issued pronouncements based on existing medical evidence that conclusively expose the known falsity of these Defendants' misrepresentations.

197. The marketing scheme to increase opioid prescriptions centered around nine categories of misrepresentations, which are discussed in detail below. The Manufacturing Defendants disseminated these misrepresentations through various channels, including through advertising, sales representatives, purportedly independent organizations these defendants funded and controlled ("Front Groups"), KOLs, and CME programs discussed below.

**A. The Manufacturer Defendants Promoted Multiple Falsehoods about Opioids**

198. The Manufacturer Defendants' misrepresentations fall into the following nine categories:

a. The risk of addiction from chronic opioid therapy is low

b. To the extent there is a risk of addiction, it can be easily identified and managed

c. Signs of addictive behavior are "pseudo addiction," requiring more opioids

d. Opioid withdrawal can be avoided by tapering

e. Opioid doses can be increased without limit or greater risks

f. Long-term opioid use improves functioning

g. Alternative forms of pain relief pose greater risks than opioids

h. OxyContin provides twelve hours of pain relief

i. New formulations of certain opioids successfully deter abuse

199. Each of these propositions was false. The Manufacturing Defendants knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

200. The foregoing categories of misrepresentations are offered to organize the numerous statements the Manufacturing Defendants made and to explain their role in the overall marketing effort, not as a checklist for assessing each Manufacturing Defendant's liability. While each Manufacturing Defendant deceptively promoted their opioids specifically, and, together with other Manufacturing Defendants, opioids generally, not every Manufacturing Defendant propagated (or needed to propagate) each misrepresentation. Each Manufacturing Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risks and benefits of opioids. While this Complaint endeavors to document examples of each Manufacturing Defendant's misrepresentations and the

manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Manufacturing Defendant.

### *1. Falsehood #1: The risk of addiction from chronic opioid therapy is low*

201. Central to the Manufacturer Defendants' promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Manufacturer Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by "legitimate" pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Manufacturer Defendants and substantially contributing to the opioid epidemic.

202. Each of the Manufacturing Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them have acknowledged, retracted, or corrected their false statements.

203. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, "even at recommended dose," and the risk substantially increases with more than three months of use. As the CDC Guideline states, "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).

a. Purdue's misrepresentations regarding addiction risk

204. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its

application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this "research" in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (NEJM) in 1980.

205. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction "rare" for patients treated with opioids. They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients' records.

**ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS**

*To the Editor:* Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

Jane Porter
Hershel Jick, M.D.
Boston Collaborative Drug Surveillance Program
Boston University Medical Center
Waltham, MA 02154

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

206. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.

207. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its

source was a letter to the editor, not a peer-reviewed paper. Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Manufacturing Defendants used it to assert that their opioids were not addictive, "that's not in any shape or form what we suggested in our letter," according to Dr. Jick.

208. Purdue specifically used the Porter and Jick letter in its 1998 promotional video "I got my life back," in which Dr. Alan Spanos says "In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*." Purdue trained its sales representatives to tell prescribers that fewer than 1% of patients who took OxyContin became addicted. In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen percent, but that finding was not included by Purdue in any of its advertising, marketing, or promotional or sales material; nor was it otherwise provided by Purdue to physicians.

209. Other Defendants relied on and disseminated the same distorted messaging. The enormous impact of Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented." In particular, the authors of this letter explained:

> [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy . . .

210. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."

211. Alongside its use of the Porter and Jick letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release

announcing the release of OxyContin, for example, Purdue declared, "The fear of addiction is exaggerated."

212. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."

213. Purdue spun this baseless "legitimate use" distinction out even further in a patient brochure about OxyContin, called "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain." In response to the question "Aren't opioid pain medications like OxyContin Tablets 'addicting'?," Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes:

> Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.

214. Sales representatives marketed OxyContin as a product "to start with and to stay with." Sales representatives also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. One of Purdue's early training memos compared doctor visits to "firing at a target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim and what you want to hit!" According to the memo, the target is physician resistance based on concern about addiction: "The physician wants pain relief for these patients without addicting them to an opioid."

215. Through its unbranded website, *Partners Against Pain*, Purdue stated the following: "Current Myth: Opioid addiction (psychological dependence) is an important clinical

problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids." "Addiction risk also appears to be low when opioids are dosed properly for chronic, noncancer pain."

216. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors' objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that "it's just too addictive." May and his coworkers were trained to "refocus" doctors on "legitimate" pain patients, and to represent that "legitimate" patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less "habit-forming" than painkillers that need to be taken every four hours.

217. According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

218. With regard to addiction, Purdue's label for OxyContin has not sufficiently disclosed the true risks to, and experience of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have "abuse potential" and that the "risk of abuse is increased in patients with a personal or family history of substance abuse."

219. However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient.

220. In 2001, Purdue revised the indication and warnings for OxyContin, but did not go nearly as far as the FDA recommended or the known risks of the product demanded. In the United States, Purdue ceased distributing the 160 mg tablet of OxyContin.

221. In the end, Purdue narrowed the recommended use of OxyContin to situations when "a continuous, around-the-clock analgesic is needed for an extended period of time" and added a warning that "[t]aking broken, chewed, or crushed OxyContin tablets" could lead to a "potentially fatal dose." However, Purdue did not, until 2014, change the label to indicate that OxyContin should not be the first therapy, or even the first opioid, used, and did not disclose the incidence or risk of overdose and death even when OxyContin was not abused. Purdue announced the label changes in a letter to health care providers.

222. Purdue was aware that there was a perception that oxycodone is safer than morphine, but did not attempt to correct that misunderstanding and instead exploited it.

b. Endo's misrepresentations regarding addiction risk

223. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

224. Until April 2012, Endo's website for Opana, *www.opana.com*, stated that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."

225. Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER. Endo's training materials for its sales representatives in 2011 also prompted sales representatives to answer "true" to the statement that addiction to opioids is not common.

226. One of the Front Groups with which Endo worked most closely was the American Pain Foundation ("APF"), described more fully below. Endo provided substantial assistance to,

and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control ("NIPC") and its website *Painknowledge.com*, which claimed that "[p]eople who take opioids as prescribed usually do not become addicted."

227. Endo was one of the APF's biggest financial supporters, providing more than half of the $10 million APF received from opioid manufacturers during its lifespan. Endo was the sole funder of NIPC and selected APF to manage NIPC. Endo was responsible for NIPC curriculum development, web posting, and workshops, developed and reviewed NIPC content, and took a substantial role in distributing NIPC and APF materials. Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

228. Another Endo website, *PainAction.com*, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

229. In a brochure available on *Painknowledge.com* titled "*Pain: Opioid Facts*," Endo-sponsored NIPC stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted." In numerous patient education pamphlets, Endo repeated this deceptive message.

230. In a patient education pamphlet titled "*Understanding Your Pain: Taking Oral Opioid Analgesics*," Endo answers the hypothetical patient question—"What should I know about opioids and addiction?"—by focusing on explaining what addiction is ("a chronic brain disease") and what it is not ("taking opioids for pain relief"). It goes on to explain that "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction." This publication is still available online.

231. An Endo publication, *Living with Someone with Chronic Pain*, stated, "Most health care providers who treat people with pain agree that most people do not develop an addiction

problem." A similar statement appeared on the Endo website, *www.opana.com*, until at least April 2012.

232. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on *Painknowledge.com*, omitted addiction from the "common risks" of opioids, as shown below:

> **As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:**
>
> - Constipation
> - Drowsiness
> - Confusion
> - Nausea
> - Itching
> - Dizziness
> - Shortness of breath
>
> Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

c. <u>Janssen's misrepresentations regarding addiction risk</u>

233. Janssen likewise misrepresented the addiction risk of opioids. One website, *Let's Talk Pain*, states, among other things, that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding about addiction." The website carried Janssen's trademark and was copy approved and controlled by Janssen.

234. The *Let's Talk Pain* website also perpetuated the concept of pseudo addiction, associating patient behaviors such as "drug seeking," "clock watching," and "even illicit drug use or deception" with undertreated pain which can be resolved with "effective pain management."

235. A Janssen unbranded website, *PrescribeResponsibly.com*, states that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."

236. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as a "myth" the claim that opioids are addictive, and asserted as "fact" that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." Until recently, this guide was still available online.


237. Janssen's website for Duragesic included a section addressing "Your Right to Pain Relief" and a hypothetical patient's fear that "I'm afraid I'll become a drug addict." The website's response: "Addiction is relatively rare when patients take opioids appropriately."

d. Cephalon's misrepresentations regarding addiction risk.

238. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which included claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." Similarly, Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

239. For example, a 2003 Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, teaches:

> [C]hronic pain is often undertreated, particularly in the noncancer patient population …. The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.

e. Actavis's misrepresentations regarding addiction risk.

240. Through its "Learn More about customized pain control with Kadian," material, Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is "less likely" to happen in those who "have never had an addiction problem." The piece goes on to advise that a need for a "dose adjustment" is the result of tolerance, and "not addiction."

241. Training for Actavis sales representatives deceptively minimizes the risk of addiction by: (i) attributing addiction to "predisposing factors" like family history of addiction or psychiatric disorders; (ii) repeatedly emphasizing the difference between substance dependence and substance abuse; and (iii) using the term pseudo addiction, which, as described below, dismisses evidence of addiction as the undertreatment of pain and, dangerously, counsels doctors to respond to its signs with more opioids.

242. Actavis conducted a market study on takeaways from prescribers' interactions with Kadian sales representatives. The doctors had a strong recollection of the sales representatives' discussion of the low-abuse potential. Actavis' sales representatives' misstatements on the low-abuse potential was considered an important factor to doctors, and was most likely repeated and reinforced to their patients. Additionally, doctors reviewed visual aids that the Kadian sales

representatives used during the visits, and Actavis noted that doctors associate Kadian with less abuse and no highs, in comparison to other opioids. Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis's messaging about Kadian's purported low addiction potential, and that it had less abuse potential than other similar opioids.

243. A guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements: (i) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and (ii) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." These statements falsely convey both that (i) Kadian does not cause euphoria and therefore is less addictive and that (ii) Kadian is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse deterrent, and Actavis had no studies to suggest it was.

f. Mallinckrodt's misrepresentations regarding addiction risk

244. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through C.A.R.E.S. Alliance.

245. Mallinckrodt in 2010 created the C.A.R.E.S. Alliance (the initials stand for "Collaborating and Acting Responsibly to Ensure Safety"), which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." "C.A.R.E.S.

Alliance" is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

246. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online. The false claims and misrepresentations in this book include the following statements:

a. "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

b. "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."

c. "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."

d. "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."

e. "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

f. "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

g. "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

247. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that, "[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated" and cites to a report that concludes that "the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others."

248. Manufacturing Defendants' suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme, but are at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who "doctor-shop"—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing and irresponsible distribution of the drugs.

***2. Falsehood #2: To the extent there is a risk of addiction, it can be easily identified and managed***

249. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Manufacturer Defendants asserted that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of

substance use, mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients.

250. Purdue provided to prescribers its *Partners Against Pain* "Pain Management Kit," which contains several screening tools, and catalogues of Purdue materials, which included these tools. Janssen, on its website PrescribeResponsibly.com, states that the risk of opioid addiction "can usually be managed" through tools such as opioid agreements between patients and doctors. The website, which directly provides screening tools to prescribers for risk assessments, includes a "[f]our question screener" to purportedly help physicians identify and address possible opioid misuse.

251. Purdue and Cephalon sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed."

252. Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, a KOL discussed below, entitled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

253. Purdue sponsored a 2011 CME program titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."

254. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed prescribers that, through the use of screening tools, more frequent refills,

and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

255. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* ("ORT") created by Dr. Webster and linked to Janssen or (b) the *Screener and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. The ORT was linked to by Endo-supported websites.

256. There are three fundamental flaws in the Manufacturer Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

#### ***3. Falsehood #3: Signs of addictive behavior are "pseudo addiction," requiring more opioids***

257. The Manufacturing Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. In 1989, Dr. Haddox, who later became a Senior Medical Director for Purdue, coined the term "pseudo addiction," which he described as "the iatrogenic syndrome

of abnormal behavior developing as a direct consequence of inadequate pain management." In plain English, the notion underlying "pseudo addiction" is that people on prescription opioids who exhibit classic signs of addiction—for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—are not "addicted," but rather are simply suffering from undertreatment of their pain, which calls for more opioids.

258. In the materials and outreach they produced, sponsored, or controlled, Defendants made each of these misrepresentations and omissions, and have never acknowledged, retracted, or corrected them.

259. Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards' ("FSMB") *Responsible Opioid Prescribing* (2007) written by Dr. Scott Fishman ("Dr. Fishman"), a KOL discussed below, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of "pseudo addiction."

260. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its website, *PartnersAgainstPain.com*, in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but "pseudo addiction" caused by untreated pain.

261. Purdue sales representatives were trained and tested on the meaning of pseudo addiction, which they in turn communicated to prescribers.

262. Purdue's Pain Management Kit endorses the concept of pseudo addiction by claiming that "pain-relief seeking behavior can be mistaken for drug-seeking behavior." The kit was in use from roughly 2011 through at least June 2016.

263. Similarly, Endo trained its sales representatives to promote the concept of pseudo addiction. A training module taught sales representatives that addiction and pseudo addiction were commonly confused. The module went on to state that: "The physician can differentiate addiction from pseudo addiction by speaking to the patient about his/her pain and increasing the patient's opioid dose to increase pain relief."

264. Endo also sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudo addiction and listed "[d]ifferentiation among states of physical dependence, tolerance, pseudo addiction, and addiction" as an element to be considered in awarding grants to CME providers.

265. The pseudo addiction concept has never been empirically validated and in fact has been abandoned by some of its proponents. The New York Attorney General, in a 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudo addiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudo addiction.'" Endo thereafter agreed not to "use the term 'pseudo addiction' in any training or marketing" in New York.

266. Janssen sponsored, funded, and edited a website called *Let's Talk Pain*, which in 2009 stated "pseudo addiction … refers to patient behaviors that may occur when *pain is undertreated* …. Pseudo addiction is different from true addiction because such behaviors can be

resolved with effective pain management." This website was accessible online until at least May 2012.

267. Janssen also currently runs a website, *Prescriberesponsibly.com*, which claims that concerns about opioid addiction are "overestimated," and describes pseudo addiction as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately the inappropriate behavior ceases."

268. The CDC Guideline nowhere recommends attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Webster admitted that pseudo addiction "is already something we are debunking as a concept" and became "too much of an excuse to give patients more medication. It led us down a path that caused harm."

#### *4. Falsehood #4: Opioid withdrawal can be avoided by tapering*

269. In an effort to downplay the risk and impact of addiction, the Manufacturing Defendants falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering patients' doses to avoid the adverse effects of withdrawal. Defendants fail to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for a prolonged period.

270. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult,* claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who have been

taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. The painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

271. Purdue sponsored the American Pain Foundation's ("APF") *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

272. To this day, the Manufacturer Defendants have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

#### ***5. Falsehood #5: Opioid doses can be increased without limit or greater risks***

273. In materials they produced, sponsored or controlled, Manufacturing Defendants instructed prescribers that they could safely increase patients' dose to achieve pain relief. Each of the Manufacturing Defendants' claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses, effects confirmed by scientific evidence.

274. These misrepresentations were integral to the Manufacturing Defendants' promotion of prescription opioids. As discussed above, patients develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose.

275. In a 1996 sales memo regarding OxyContin, for example, a regional manager for Purdue instructed sales representatives to inform physicians that there is "no[] upward limit" for dosing and ask "if there are any reservations in using a dose of 240mg-320mg of OxyContin."

276. Purdue sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

> It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."
>
> The next week the rep would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin.

277. These misrepresentations were particularly dangerous. As noted above, opioid doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. The recommendation of 320 mg every twelve hours is approximately ten times that.

278. In its 2010 Risk Evaluation and Mitigation Strategy ("REMS") for OxyContin, however, Purdue does not address the increased risk of respiratory depression and death from increasing dose, and instead advises prescribers that "dose adjustments may be made every 1-2 days"; "it is most appropriate to increase the q12h dose"; the "total daily dose can usually be increased by 25% to 50%"; and if "significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration."

279. Endo sponsored a website, *Painknowledge.com*, which claimed that opioids may be increased until "you are on the right dose of medication for your pain," at which point further dose increases would not be required.

280. Endo also published on its website a patient education pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked, "If I take

the opioid now, will it work later when I really need it?" The response is, "The dose can be increased …. You won't 'run out' of pain relief."

281. Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have "no ceiling dose" and therefore are safer than NSAIDs.

282. Manufacturer Defendants were aware of the greater dangers high dose opioids posed. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events" and that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." A study of the Veterans Health Administration from 2004 to 2008 found the rate of overdose deaths is directly related to maximum daily dose.

### ***6. Falsehood #6: Long-term opioid use improves functioning***

283. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Manufacturing Defendants consistently promoted opioids as capable of improving patients' function and quality of life because they viewed those claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

284. Janssen, for example, promoted Duragesic as improving patients' functioning and work productivity through an ad campaign that included the following statements: "[w]ork, uninterrupted," "[l]ife, uninterrupted," "[g]ame, uninterrupted," "[c]hronic pain relief that supports functionality," and "[i]mprove[s] … physical and social functioning."

285. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

> Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine…We do not have such data to support OxyContin promotion. … In addition, Janssen has been using the "life uninterrupted" message in promotion of Duragesic for non-cancer pain, stressing that Duragesic "helps patients think less about their pain." This is a competitive advantage based on our inability to make any quality of life claims.

286. Despite its acknowledgment that "[w]e do not have such data to support OxyContin promotion," Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association, proclaiming, "There Can Be Life With Relief," and showing a man happily fly-fishing alongside his grandson, implying that OxyContin would help users' function. This ad earned a warning letter from the FDA, which admonished, "It is particularly disturbing that your November ad would tout 'Life With Relief' yet fail to warn that patients can die from taking OxyContin."

287. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids."

288. A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

289. Similarly, since at least May of 2011, Endo has distributed and made available on its website, *opana.com*, a pamphlet promoting Opana ER with photographs depicting patients with

physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

290. As noted above, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as "a fact" that "opioids may make it easier for people to live normally." This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'" Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

291. In addition, Janssen's *Let's Talk Pain,* website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative.

292. The APF's *Treatment Options: A Guide for People Living with Pain* (2007), sponsored by Purdue and Cephalon, counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

293. Endo's NIPC website *Painknowledge.com* claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." In addition to "improved function," the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make claims of functional improvement.

294. Endo was the sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

295. Mallinckrodt's website, in a section on responsible use of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."

296. The Manufacturing Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life. Based upon a review of the existing scientific evidence, the CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use."

297. Consistent with the CDC's findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid use had "consistently poor results," and "several studies have showed that opioids for chronic pain may actually worsen pain and functioning …" along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

298. The available evidence indicates opioids may worsen patients' health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant." According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."

299. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally." In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work. Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all. Moreover, the first randomized clinical trial designed to make head-to-head comparisons between opioids and other kinds of pain medications was published on March 6, 2018, in the Journal of the American Medical Association. The study reported that "[t]here was no significant difference in pain-related function between the 2 groups"—those whose pain was treated with opioids and those whose pain was treated with non-opioids, including acetaminophen and other non-steroidal anti-inflammatory drugs ("NSAIDs")

like ibuprofen. Accordingly, the study concluded: "Treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months."

### *7. Falsehood #7: Alternative forms of pain relief pose greater risks than opioids*

300. In materials they produced, sponsored or controlled, the Manufacturer Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs.

301. For example, in addition to failing to disclose in promotional materials the risks of addiction, overdose, and death, the Manufacturing Defendants routinely ignored the risks of hyperalgesia (a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time"); hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth); and potentially fatal interactions with alcohol or with benzodiazepines (which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain).

302. The APF's *Treatment Options: A Guide for People Living with Pai*n, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the figure is closer to 3,200.

303. Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009), that listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased doses from opioids. *Finding Relief* described the advantages and disadvantages

of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness" (which the brochure claims will go away) and constipation.

304. Endo's NIPC website, *Painknowledge.com*, contained a flyer called "*Pain: Opioid Therapy*." This publication listed opioids' adverse effects but with significant omissions, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

305. The Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult*, discussed above, counseled that acetaminophen should be used only short-term and includes five slides on the FDA's restrictions on acetaminophen and its adverse effects, including severe liver injury and anaphylaxis (shock). In contrast, the CME downplays the risk of opioids, claiming opioids have "possibly less potential for abuse than in younger patients," and does not list overdose among the adverse effects. Some of those misrepresentations are described above; others are laid out below.

306. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News*, titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain." The article asserted:

> Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.

307. To help allay these prescriber concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended

use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

308. Additionally, Purdue acting with Endo sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

309. As a result of the Manufacturing Defendants' deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.

***8. Falsehood #8: OxyContin provides twelve hours of pain relief***

310. Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it provides the basis for both Purdue's patent and its market niche, allowing it to both protect and differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that OxyContin had a more even, stable release mechanism that avoided peaks and valleys and therefore the rush that fostered addiction and attracted abusers.

311. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of

oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart, which was apparently adapted from Purdue's own sales materials:

OxyContin PI Figure, Linear y-axis

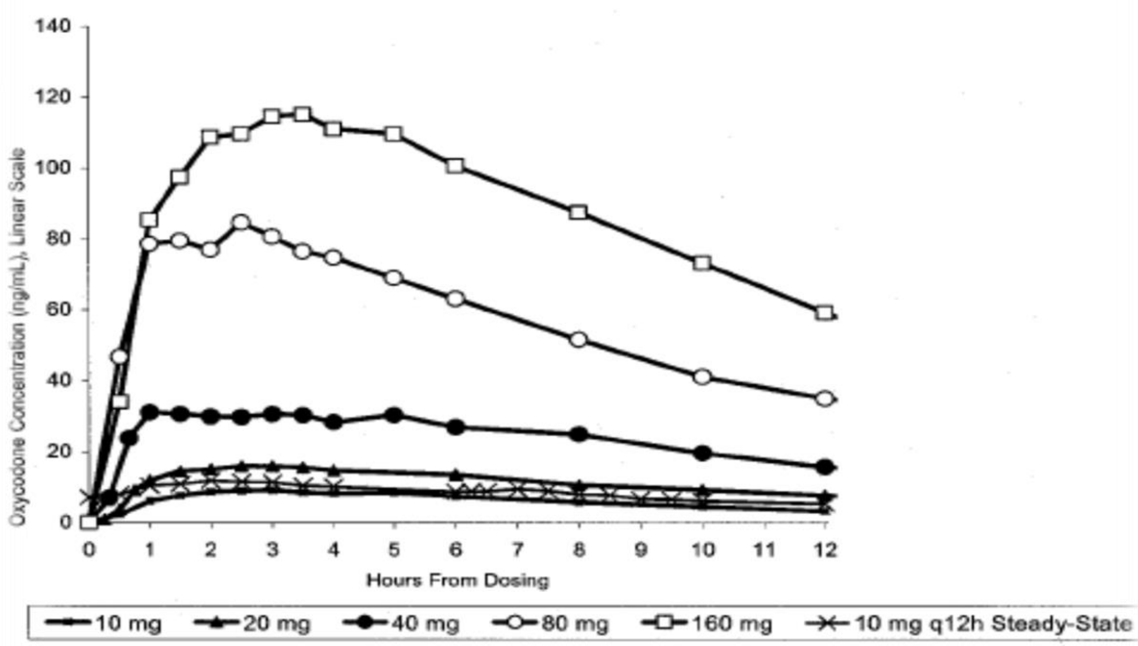



Figure 1

312. The reduced release of the drug over time means that the oxycodone no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for the twelve hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

313. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at

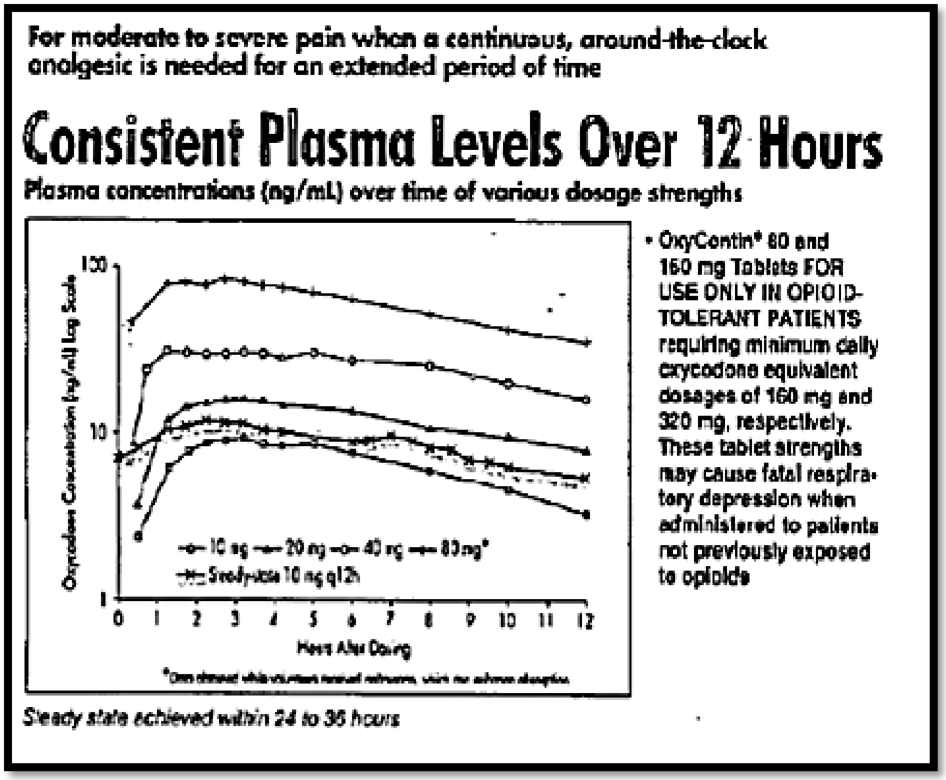
the end of the dosing period, which results in the drug not lasting for a full twelve hours and precipitates withdrawal symptoms in patients, a phenomenon known as "end of dose" failure.

314. The FDA has found that a "substantial number" of chronic pain patients will experience end-of-dose failure with OxyContin.

315. End-of-dose failure renders OxyContin particularly dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction." Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

316. It was Purdue's decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," that is because Purdue has conducted no such studies.

317. Purdue falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides "Consistent Plasma Levels Over 12 Hours." That claim was accompanied by a doctored version of the chart on the previous page. The doctored version deceptively minimized the rate of end-of-dose failure by depicting 10 mg in the table's y-axis as if it were half of 100 mg. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:




318. Purdue's 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important benefit."

319. Purdue executives maintained the messaging of twelve-hour dosing even when many reports surfaced that OxyContin did not, in fact, last twelve hours. Instead of acknowledging a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills, even though higher dosing carries its own risks, as noted above. It also means that patients will

experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED that the CDC Guideline urges prescribers to "avoid" or "carefully justify."

320. The information that OxyContin did not provide pain relief for a full twelve hours was known to Purdue, and Purdue's competitors, but was not disclosed to prescribers. Purdue's knowledge of some pain specialists' tendency to prescribe OxyContin three times per day instead of two was set out in Purdue's internal documents as early as 1999 and is apparent from MEDWATCH Adverse Event reports for OxyContin.

321. Even Purdue's competitor, Endo, was aware of the problem; Endo attempted to position its Opana ER drug as offering "durable" pain relief, which Endo understood to suggest a contrast to OxyContin. Opana ER advisory board meetings featured pain specialists citing lack of 12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to "real" 12-hour dosing.

322. For example, in a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should "convinc[e] the physician that there is no need" for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and instead the solution is prescribing higher doses." One sales manager instructed her team that anything shorter than 12-hour dosing "needs to be nipped in the bud. NOW!!"

323. Purdue's failure to disclose the prevalence of end-of-dose failure meant that prescribers were misinformed about the advantages of OxyContin in a manner that preserved Purdue's competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

***9. Falsehood #9: New formulations of certain opioids successfully deter abuse***

324. Rather than take the widespread abuse of and addiction to opioids as reason to cease their untruthful marketing efforts, Manufacturing Defendants Purdue and Endo seized them as a competitive opportunity. These companies developed and oversold "abuse-deterrent formulations" ("ADF") opioids as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids, as well as an advantage of these expensive branded drugs over other opioids. These Defendants' false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales and falsely reassured prescribers thereby prolonging the opioid epidemic. Other Manufacturing Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less subject to abuse than other opioids.

325. The CDC Guideline confirms that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes." Tom Frieden, the former Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."

g. <u>Purdue's deceptive marketing of reformulated OxyContin and Hysingla ER</u>

326. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a citizen petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations. But in the beginning, the FDA made clear the limited claims that could be made about ADF, noting that no evidence supported claims that ADF prevented tampering, oral abuse, or overall rates of abuse.

327. This reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Purdue, however, touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the problem of opioid abuse.

328. Despite its self-proclaimed good intention, Purdue merely incorporated its generally deceptive tactics with respect to ADF. Purdue sales representatives regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue sales representatives falsely:

a. claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;

b. claimed that Purdue's ADF opioids reduce opioid abuse and diversion;

c. asserted or suggested that its ADF opioids are non-addictive or less addictive,

d. asserted or suggested that Purdue's ADF opioids are safer than other opioids, could not be abused or tampered with, and were not sought out for diversion; and

e. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

329. If pressed, Purdue acknowledged that perhaps some "extreme" patients might still abuse the drug, but claimed the ADF features protect the majority of patients. These misrepresentations and omissions are misleading and contrary to Purdue's ADF labels, Purdue's own information, and publicly available data.

330. Purdue knew or should have known that reformulated OxyContin is not more tamper-resistant than the original OxyContin and is still regularly tampered with and abused.

331. In 2009, the FDA noted, in permitting ADF labeling, that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." In

the 2012 medical office review of Purdue's application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption and only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

332. The FDA's Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin "actually made a reduction in abuse," between continued oral abuse, shifts to injection of other drugs (including heroin), and defeat of the ADF mechanism. Even Purdue's own funded research shows that half of OxyContin abusers continued to consume the drug orally after the reformulation rather than shift to other drugs.

333. A 2013 article presented by Purdue employees based on review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, but it ignored important negative findings. The study revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

334. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. Purdue has been aware of these methods of abuse for more than a decade.

335. One-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF

opioids was reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to other opioids such as heroin.

336. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse." Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

337. Despite its own evidence of abuse, and the lack of evidence regarding the benefit of Purdue's ADF opioids in reducing abuse, Dr. Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers. Purdue's recent advertisements in national newspapers also continues to claim its ADF opioids as evidence of its efforts to reduce opioid abuse, continuing to mislead prescribers, patients, payors, and the public about the efficacy of its actions.

h. Endo's deceptive marketing of reformulated Opana ER

338. As the expiration of its patent exclusivity for Opana ER neared, Endo also made abuse-deterrence a key to its marketing strategy.

339. Opana ER was particularly likely to be tampered with and abused. That is because Opana ER has lower "bioavailability" than other opioids, meaning that the active pharmaceutical ingredient (the "API" or opioid) does not absorb into the bloodstream as rapidly as other opioids when taken orally. Additionally, when swallowed whole, the extended-release mechanism remains intact, so that only 10% of Opana ER's API is released into the patient's bloodstream relative to

injection; when it is taken intranasally, that rate increases to 43%. The larger gap between bioavailability when consumed orally versus snorting or injecting, the greater the incentive for users to manipulate the drug's means of administration.

340. Endo knew by July 2011 that "some newer statistics around abuse and diversion are not favorable to our product."

341. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant.

342. Even prior to its approval, the FDA had advised Endo that it could not market the new Opana ER as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. Indeed, Endo's own studies dating from 2009 and 2010 showed that Opana ER could be crushed and ground, and, in its correspondence with the FDA, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

343. Further, a January 4, 2011 FDA Discipline Review letter made clear to Endo that "[t]he totality of these claims and presentations suggest that, as a result of its new formulation, Opana ER offers a therapeutic advantage over the original formulation when this has not been demonstrated by substantial evidence or substantial clinical experience. In addition, these claims misleadingly minimize the risks associated with Opana ER by suggesting that the new formulation's "INTAC" technology confers some form of abuse-deterrence properties when this has not been demonstrated by substantial evidence." The FDA acknowledged that while there is "evidence to support some limited improvement" provided by the new coating, it would not let Endo promote any benefit because "there are several limitations to this data." Also, Endo was

required to add language to its label specifically indicating that "Opana ER tablets may be abused by crushing, chewing, snorting, or injecting the product. These practices will result in less controlled delivery of the opioid and pose a significant risk to the abuser that could result in overdose and death."

344. The FDA expressed similar concerns in nearly identical language in a May 7, 2012 letter to Endo responding to a February 2, 2012, "request … for comments on a launch Draft Professional Detail Aid … for Opana ER." The FDA's May 2012 letter also includes a full two pages of comments regarding "Omissions of material facts" that Endo left out of the promotional materials.

345. Endo consciously chose not to do any post-approval studies that might satisfy the FDA. According to internal documents, the company decided, by the time its studies would be done, generics would be on the market and "any advantages for commercials will have disappeared." However, this lack of evidence did not deter Endo from marketing Opana ER as ADF while its commercial window remained open.

346. Nonetheless, in August of 2012, Endo submitted a citizen petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted and that it was resistant to injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse-deterrence), which would prevent generic copies of original Opana ER.

347. Endo then sued the FDA, seeking to force expedited consideration of its citizen petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would

decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare" would be lost. The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."

348. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."

349. In its citizen petition, Endo asserted that redesigned Opana ER had "safety advantages." Endo even relied on its rejected assertion that Opana was less crushable to argue that it developed Opana ER for patient safety reasons and that the new formulation would help, for example, "where children unintentionally chew the tablets prior to an accidental ingestion."

350. However, in rejecting the petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injections and more easily injected[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

351. Meanwhile, in 2012, an internal memorandum to Endo account executives noted that abuse of Opana ER had "increased significantly" in the wake of the purportedly abuse-

deterrent formulation. In February 2013, Endo received abuse data regarding Opana ER from Inflexxion, Inc., which gathers information from substance abusers entering treatment and reviews abuse-focused internet discussions, that confirmed continued abuse, particularly by injection.

352. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500%. Endo's own data, presented in 2014, found between October 2012 and March 2014, 64% of abusers of Opana ER did so by injection, compared with 36% for the old formulation. The transition into injection of Opana ER made the drug even less safe than the original formulation. Injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.

353. Publicly, Endo sought to marginalize the problem. On a 2013 call with investors, when asked about an outbreak of TTP in Tennessee from injecting Opana ER, Endo sought to limit its import by assigning it to "a very, very distinct area of the country."

354. Despite its knowledge that Opana ER was widely abused and injected, Endo marketed the drug as tamper-resistant and abuse-deterrent. Upon information and belief, based on the company's detailing elsewhere, Endo sales representatives informed doctors that Opana ER was abuse-deterrent, could not be tampered with, and was safe. In addition, sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while outlier patients might find a way to abuse the drug, most would be protected.

355. A review of national surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant. Endo also tracked messages that doctors took from its in-person marketing. Among the

advantages of Opana ER, according to participating doctors, was its "low abuse potential." An internal Endo document also notes that market research showed that, "[l]ow abuse potential continues as the primary factor influencing physicians' anticipated increase in use of Opana ER over the next 6 months."

356. In its written materials, Endo marketed Opana ER as having been designed to be crush-resistant, knowing that this would (falsely) imply that Opana ER actually was crush-resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its Opana ER franchise to the new formulation designed to be crush resistant."

357. The press release further stated that: "We firmly believe that the new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers." The press release described the old formulation of Opana as subject to abuse and misuse, but failed to disclose the absence of evidence that reformulated Opana was any better. In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."

358. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the *Pain Medicine News* website, which was accessible to patients and prescribers.

359. In March 2017, because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017. Endo

announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER. However, by this point, the damage had been done. Even then, Endo continued to insist, falsely, that it "has taken significant steps over the years to combat misuse and abuse."

i. Other Manufacturer Defendants' misrepresentations regarding abuse deterrence

360. A guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide declares that the "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and "KADIAN may be less likely to be abused by health care providers and illicit users" because of its "[s]low onset of action." Kadian, however, was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

361. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving." One member of the FDA's Controlled Substance Staff, however, noted in 2010 that hydromorphone has "a high abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion."

362. With respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients." In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."

363. While Manufacturing Defendants promote patented technology as the solution to opioid abuse and addiction, none of their "technology" addresses the most common form of abuse—oral ingestion—and their statements regarding abuse-deterrent formulations give the misleading impression that these reformulated opioids can be prescribed safely.

364. In sum, each of the nine categories of misrepresentations discussed above regarding the use of opioids to treat chronic pain was not supported by or was contrary to the scientific evidence. In addition, the misrepresentations and omissions set forth above and elsewhere in this Complaint are misleading and contrary to the Manufacturer Defendants' products' labels.

**B. The Manufacturer Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Channels**

365. The Manufacturer Defendants' false marketing campaign not only targeted the medical community who had to treat chronic pain, but also patients who experience chronic pain.

366. The Manufacturer Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1)Front Groups with the false appearance of independence from the Manufacturer Defendants; (2) KOLs, that is, doctors who were paid by the Manufacturer Defendants to promote their pro-opioid message; (3) CME programs controlled and/or funded by the Manufacturer Defendants; (4) branded advertising; (5) unbranded advertising; (6) publications; (7) direct, targeted communications with prescribers by sales representatives; and (8) speakers bureaus and programs.

***1. The Manufacturer Defendants Directed Front Groups to Deceptively Promote Opioid Use***

367. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Manufacturer Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These Front Groups put out patient education

materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies.

368. Patient advocacy organizations and professional societies like the Front Groups play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public. Even small organizations—with their large numbers and credibility with policymakers and the public—have extensive influence in specific disease areas. Larger organizations with extensive funding and outreach capabilities likely have a substantial effect on policies relevant to their industry sponsors.

369. The Manufacturing Defendants made millions of dollars' worth of contributions to various Front Groups.

370. The Manufacturing Defendants also "made substantial payments to individual group executives, staff members, board members, and advisory board members" affiliated with the Front Groups.

371. The Front Groups amplified or issued messages that reinforced industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain. They also lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for over prescription and misbranding.

372. The Manufacturer Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and through the Front Groups, with each other to deceptively promote the use of opioids for the treatment of chronic pain.

a. American Pain Foundation

373. The most prominent of the Front Groups was the American Pain Foundation ("APF"). While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from defendants Purdue, Endo, Janssen and Cephalon. APF received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its $10 million in funding from 2007 to 2012.

374. For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain*, and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use, which are discussed below.

375. APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, *www.painknowledge.com*. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from

pharmaceutical companies), including a series of "dinner dialogues." But Endo substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it as one of its "professional education initiative[s]" in a plan Endo submitted to the FDA. Yet, Endo's involvement in NIPC was not disclosed anywhere on the website pages describing NIPC or *www.painknowledge.org*. Endo estimated it would reach 60,000 prescribers through NIPC.

376. APF was often called upon to provide "patient representatives" for the Manufacturing Defendants' promotional activities, including for Purdue's "Partners Against Pain" and Janssen's "Let's Talk Pain." Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Manufacturing Defendants, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue's desire to strategically align its investments in nonprofit organizations that share [its] business interests.

377. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

378. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement (the "Agreement") on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the Agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The Agreement gave Purdue—but not APF—the right to end the

project (and, thus, APF's funding) for any reason. Even for projects not produced during the terms of this Agreement, the Agreement demonstrates APF's lack of independence and willingness to harness itself to Purdue's control and commercial interests, which would have carried across all of APF's work.

379. APF's Board of Directors was largely comprised of doctors who were on the Manufacturing Defendants' payrolls, either as consultants or speakers at medical events. The close relationship between APF and the Manufacturing Defendants demonstrates APF's clear lack of independence in its finances, management, and mission and its willingness to allow Manufacturing Defendants to control its activities and messages supports an inference that each Defendant that worked with APF was able to exercise editorial control over its publications—even when Defendants' messages contradicted APF's internal conclusions. For example, a roundtable convened by APF and funded by Endo also acknowledged the lack of evidence to support chronic opioid therapy. APF's formal summary of the meeting notes concluded that: "[An] important barrier[] to appropriate opioid management [is] the lack of confirmatory data about the long-term safety and efficacy of opioids in non-cancer chronic pain, amid cumulative clinical evidence."

380. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately." Without support from Manufacturer Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.

b. American Academy of Pain Medicine and the American Pain Society

381. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding

from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The Chair of the committee that issued the statement, Dr. Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy ("Dr. Portenoy"), who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

382. AAPM's corporate council includes Purdue, Depomed, Teva, and other pharmaceutical companies. AAPM's past presidents include Dr. Haddox (1998), Dr. Fishman (2005), Dr. Perry G. Fine (" Dr. Fine") (a KOL discussed below) (2011) and Dr. Webster (2013), all of whose connections to the opioid manufacturers are well-documented as set forth herein.

383. Dr. Fishman, who also served as a KOL for Manufacturing Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are … small and can be managed."

384. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations.

385. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to

doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone.

386. AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

387. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines"). AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

388. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

389. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who also served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

390. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were

reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Manufacturing Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."

391. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.

392. The Manufacturing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines, or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

c. Federation of State Medical Boards

393. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

394. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

395. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies." The 1998 Guidelines that the pharmaceutical companies helped author taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

396. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Plaintiff's Community.

397. FSMB's 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. The publication also received support from the American Pain Foundation and the AAPM. The publication was written by Dr. Fishman, and Dr. Fine both of whom served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as "the leading continuing medical education (CME) activity for prescribers of opioid medications." This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.

398. The Manufacturing Defendants relied on the 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to treat patients' chronic pain.

d. The Alliance for Patient Access

399. Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care." It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006. As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list includes J&J (parent of Janssen), Endo, Mallinckrodt, Purdue, and Cephalon. References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

400. APA's board members have also directly received substantial funding from pharmaceutical companies. For instance, board vice president Dr. Srinivas Nalamachu ("Dr. Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids' side effects, including from defendants Endo, Insys, Purdue, and Cephalon. Dr. Nalamachu's clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys. Other board members include Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015

from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

401. Among its activities, APA issued a "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse." Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

> Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.
>
> ….
>
> In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives ….
>
> We cannot merely assume that these programs will reduce prescription pain medication use and abuse.

402. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have

a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements …. [I]t is not even certain that the regulations are helping prevent abuses.

403. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong—or even criminal …. Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management—a situation fueled by the numerous regulations and fines that surround prescription pain medications.

404. In conclusion, the white paper states that "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."

405. The APA also issues "Patient Access Champion" financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a $7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients' access to Medicare, and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they appear to be given to provide cover to and reward members of Congress who have supported the APA's agenda.

406. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* ("CSA" or "Controlled Substances Act"). The AAPM is also a signatory to this letter. An internal U.S. Department of Justice ("DOJ") memo stated that the

proposed bill "'could actually result in increased diversion, abuse, and public health and safety consequences'" and, according to DEA chief administrative law judge John J. Mulrooney ("Mulrooney"), the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like the defendants here, in the federal courts. The law passed both houses of Congress and was signed into law in 2016.

e. The U.S. Pain Foundation

407. The U.S. Pain Foundation ("USPF") was another Front Group with systematic connections and interpersonal relationships with the Manufacturer Defendants. The USPF was one of the largest recipients of contributions from the Manufacturer Defendants, collecting nearly $3 million in payments between 2012 and 2015 alone. The USPF was also a critical component of the Manufacturer Defendants' lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to the Manufacturer Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (i.e. Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members. Industry Front Groups like the American Academy of Pain Management, the AAPM, the APS, and PhRMA are also members of varying levels in the USPF.

f. American Geriatrics Society

408. The American Geriatrics Society ("AGS") was another Front Group with systematic connections and interpersonal relationships with the Manufacturer Defendants. The AGS was a large recipient of contributions from the Manufacturer Defendants, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (The Management of Persistent Pain in Older Persons, hereinafter "2002 AGS Guidelines") and 2009 (Pharmacological Management of Persistent Pain in Older Persons, hereinafter "2009 AGS Guidelines"). According to news reports,

AGS has received at least $344,000 in funding from opioid manufacturers since 2009. AGS's complicity in the common purpose with the Manufacturer Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive-up front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

409. The 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain … should be considered for opioid therapy." The panel made "strong recommendations" in this regard despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. These Guidelines further recommended that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 1,833 times in Google Scholar (which allows users to search scholarly publications that would have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

410. Representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

411. Members of AGS Board of Directors were doctors who were on the Manufacturer Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

### *2. The Manufacturer Defendants Paid KOLs to Deceptively Promote Opioid Use*

412. To falsely promote their opioids, the Manufacturer Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Manufacturer Defendants for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Manufacturer Defendants' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception science and legitimate medical professionals favored the wider and broader use of opioids. These doctors include Dr. Portenoy and Dr. Webster, as set forth in this section, as well as Dr. Fine and Dr. Fishman, as set forth further below.

413. Although these KOLs were funded by the Manufacturer Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

414. As the Manufacturer Defendants' false marketing scheme picked up steam, these pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

415. Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Manufacturer Defendants were able to exert control of each of these modalities through which doctors receive their information.

416. In return for their pro-opioid advocacy, the Manufacturer Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster has received funding from Endo, Purdue, and Cephalon. Dr. Fine has received funding from Janssen, Cephalon, Endo, and Purdue.

417. The Manufacturer Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Manufacturer Defendants' agenda. The Manufacturer Defendants also kept close tabs on the content of the materials published by these KOLs. And, of course, the Manufacturer Defendants kept these KOLs well-funded to enable them to push the Manufacturer Defendants' deceptive message out to the medical community.

418. Once the Manufacturer Defendants identified and funded KOLs and those KOLs began to publish "scientific" papers supporting the Manufacturer Defendants' false position that opioids were safe and effective for treatment of chronic pain, the Manufacturer Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies and articles by their KOLs to drive prescription of opioids for chronic pain. The Manufacturer Defendants cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Manufacturer Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

419. In their promotion of the use of opioids to treat chronic pain, the Manufacturer Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Manufacturer Defendants.

g. Dr. Portenoy

420. In 1986, Dr. Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."

421. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

> *The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs.* This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*

(emphasis added). According to Dr. Portenoy, the foregoing problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."

422. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Manufacturer Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him "lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak.

It was a compelling message: 'Docs have been letting patients suffer; nobody really gets addicted; it's been studied.'"

423. As one organizer of CME seminars who worked with Dr. Portenoy and Purdue pointed out, "had Portenoy not had Purdue's money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue's millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified."

424. Dr. Portenoy was also a critical component of the Manufacturer Defendants' control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

425. In recent years, some of the Manufacturer Defendants' KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature. Dr. Portenoy has now admitted that he minimized the risks of opioids, and that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." He mused, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did …."

426. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.*

427. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."

h. Dr. Webster

428. Another KOL, Dr. Webster was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo's special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon).

429. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool ("ORT") appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended the use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in Cuyahoga County.

430. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from

overdoses. In keeping with the Manufacturer Defendants' promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.

431. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Dr. Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP." This CME effectively amounted to off-label promotion of Cephalon's opioids—the only drugs in this category—for chronic pain, even though they were approved only for cancer pain.

432. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

i. Dr. Fine

433. Dr. Fine's ties to the Manufacturer Defendants have been well documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other

drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.

434. Multiple videos feature Dr. Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death of a drug overdose.

435. He has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under $5,000 in 2010 from J&J for providing "educational" services, but J&J's website states that the company paid him $32,017 for consulting, promotional talks, meals and travel that year.

436. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction:

> At clinically appropriate doses … respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.
>
> Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.

437. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study." In that article, Dr. Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain." The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids

for the management of chronic noncancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."

438. The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." They also conclude that the number of abuse-related events was "small."

439. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled "Optimizing Opioid Therapy," he sets forth a "Guideline for Chronic Opioid Therapy" discussing "opioid rotation" (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person's "lifetime" to manage pain. He states the "goal is to improve effectiveness which is different from efficacy and safety." Rather, for chronic pain patients, effectiveness "is a balance of therapeutic good and adverse events *over the course of years*." The entire program assumes that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with "tools," but leaves that for "a whole other lecture."

j. Dr. Fishman

440. Dr. Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed below, he

has authored publications, including the seminal guides on opioid prescribing, which were funded by the Manufacturer Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."

441. Dr. Fishman authored a physician's guide on the use of opioids to treat chronic pain titled "Responsible Opioid Prescribing," in 2007 which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

442. In 2012, Dr. Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

> Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever.

443. The updated guide still assures that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins."

444. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict." The guide also continues to present symptoms of addiction as symptoms of "pseudo addiction."

### *3. The Manufacturer Defendants Disseminated Their Misrepresentations Through Continuing Medical Education*

445. Once the Manufacturer Defendants had assembled a group of physician promoters and built a false body of "literature," they needed to make sure their false marketing message was widely distributed. One way the Manufacturer Defendants did so was through CMEs.

446. A CME is a professional education program provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, online, and through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

447. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Manufacturer Defendants' deceptions.

448. The Manufacturer Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

449. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians across the country.

450. Another Cephalon-sponsored CME presentation titled *Breakthrough Pain: Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who "previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway." The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

451. Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

452. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo and Teva. The FSMB website described it as the "leading continuing medical education (CME) activity for prescribers of opioid medications." Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Fishman.

453. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

454. The American Medical Association ("AMA") recognized the impropriety that pharmaceutical company-funded CMEs creates; stating that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."

455. Physicians attended or reviewed CMEs sponsored by the Manufacturer Defendants during the relevant time period and were misled by them.

456. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Manufacturer Defendants could expect instructors to deliver messages favorable to them, as these organizations were dependent on the Manufacturer Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Manufacturing Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and the Manufacturer Defendants both measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

***4. The Manufacturer Defendants Used "Branded" Advertising to Promote their Products to Doctors and Consumers***

457. The Manufacturer Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Manufacturer Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such

as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. The Manufacturer Defendants collectively spent more than $14 million on the medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

458. The Manufacturer Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it. They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved. Endo's research, for example, also found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. The Manufacturer Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials in the form of pamphlets, videos, or other publications that patients could view in their physician's office.

***5. The Manufacturer Defendants Used "Unbranded" Advertising To Promote Opioid Use For Chronic Pain Without FDA Review***

459. The Manufacturer Defendants also aggressively promoted opioids through "unbranded advertising" to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as "disease awareness"—encouraging consumers to "talk to your doctor" about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a pharmaceutical company's "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA

Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's FDA-approved label. Through unbranded materials, the Manufacturer Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

460. Many of the Manufacturer Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue's pain-management website, *www.inthefaceofpain.com*. The website contained testimonials from several dozen "advocates," including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

***6. The Manufacturer Defendants Funded, Edited and Distributed Publications That Supported Their Misrepresentations***

461. The Manufacturer Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

462. To accomplish their goal, the Manufacturer Defendants—sometimes through third-party consultants and/or Front Groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

463. The Manufacturer Defendants' plans for these materials did not originate in the departments with the organizations that were responsible for research, development, or any other

area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in the Manufacturer Defendants' marketing departments.

464. The Manufacturer Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Manufacturer Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Manufacturer Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

465. The Manufacturer Defendants published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

466. For example, in 2007 Cephalon sponsored the publication of an article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate," published in the nationally circulated journal *Pain Medicine*, to support its effort to expand the use of its branded fentanyl products. The article's authors (including Dr. Webster) stated that the "OTFC [fentanyl] has been shown to relieve BTP more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients." The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Dr. Portenoy and recommends fentanyl for non-cancer BTP patients:

> In summary, BTP appears to be a clinically important condition in patients with chronic noncancer pain and is associated with an adverse impact on QoL. This qualitative study on the

negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.

### *7. The Manufacturer Defendants Used Sales Representatives to Directly Disseminate Their Misrepresentations to Prescribers*

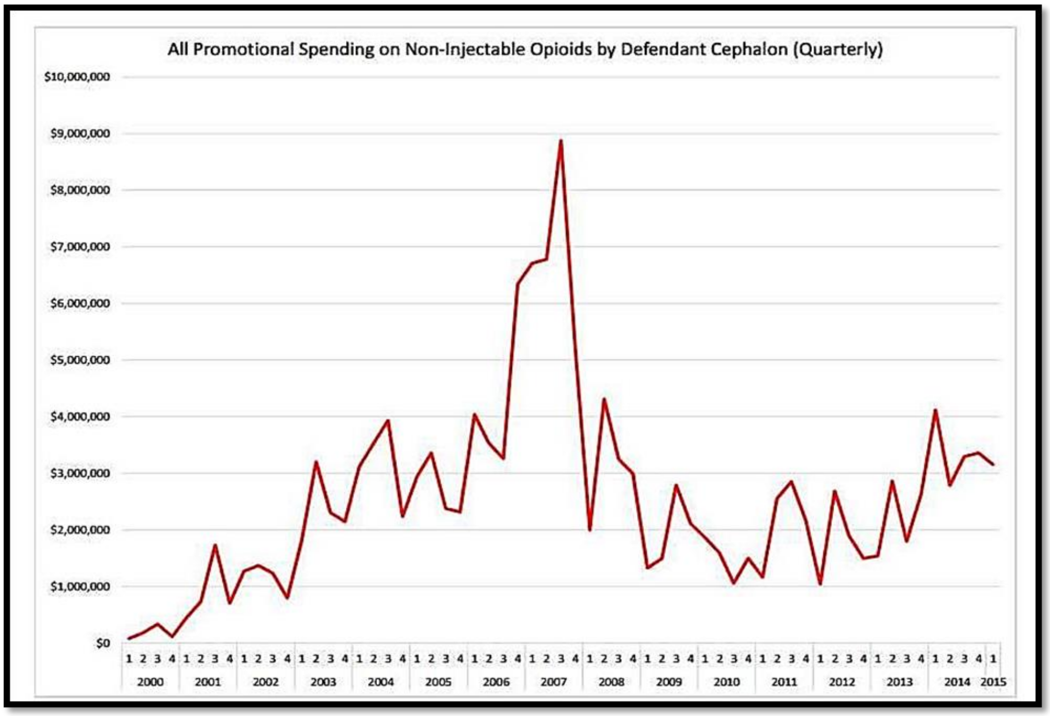
467. The Manufacturer Defendants' sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors with centrally orchestrated messages. The Manufacturer Defendants' sales representatives also distributed third-party marketing material to their target audience that was deceptive.

468. Each Manufacturing Defendant promoted opioids through sales representatives (also called "detailers") and, upon information and belief, small group speaker programs to reach out to individual prescribers. By establishing close relationships with doctors, the Manufacturer Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

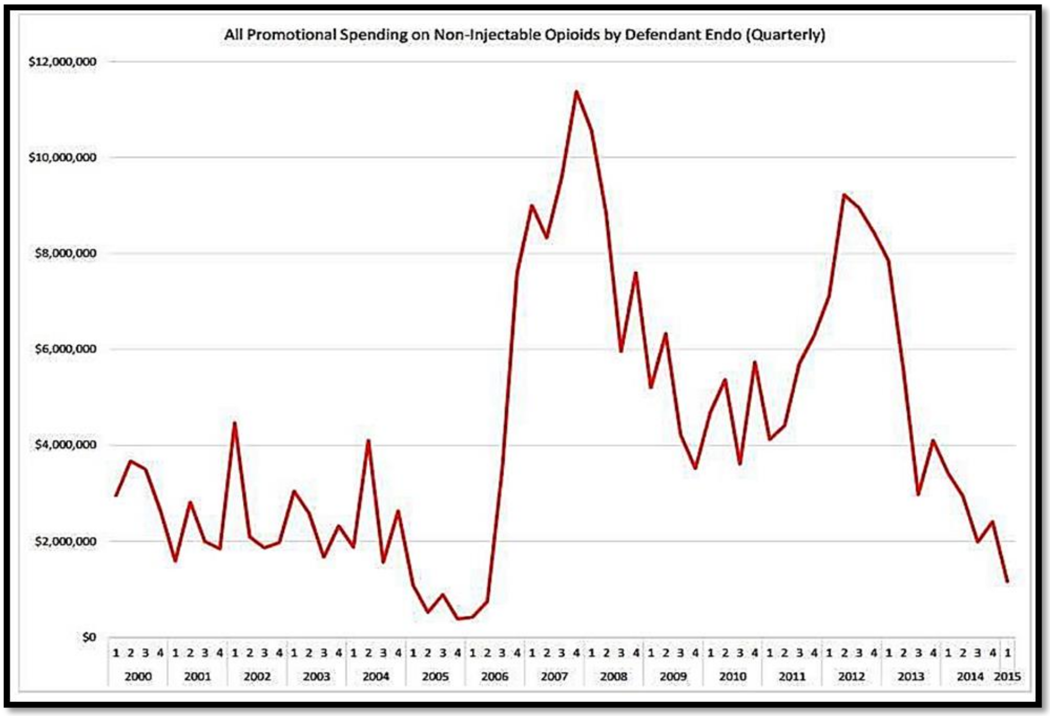
469. In accordance with common industry practice, the Manufacturer Defendants purchase and closely analyze prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

470. Manufacturer Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturer Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturer Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo.

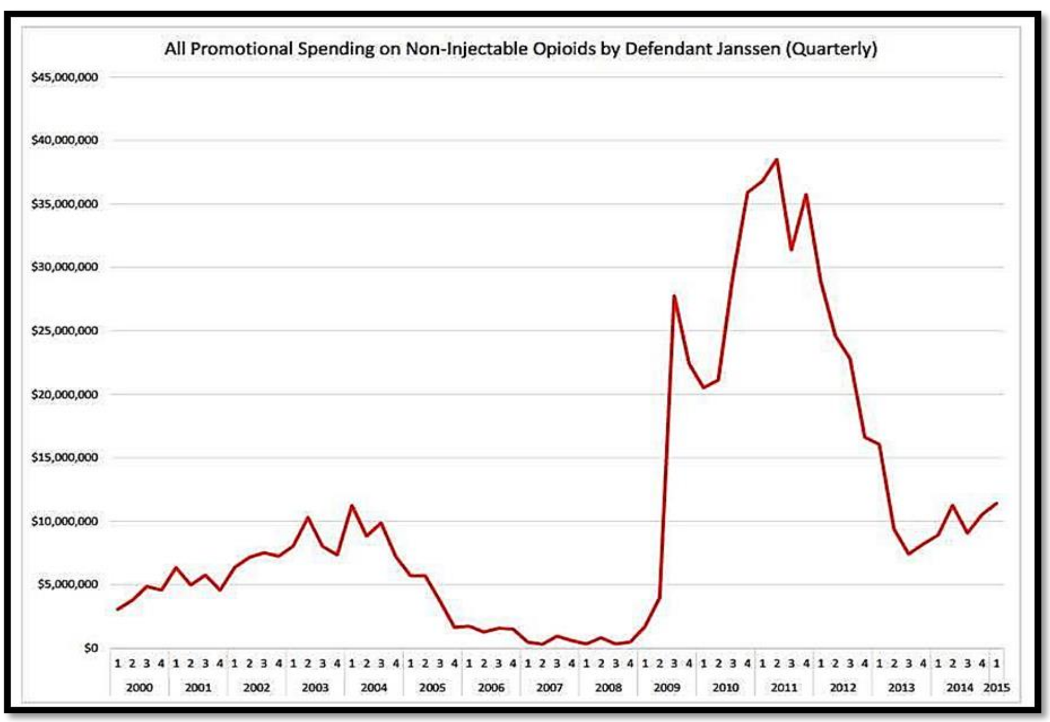
471. Cephalon's quarterly spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of more than $27 million in 2007, as shown below:



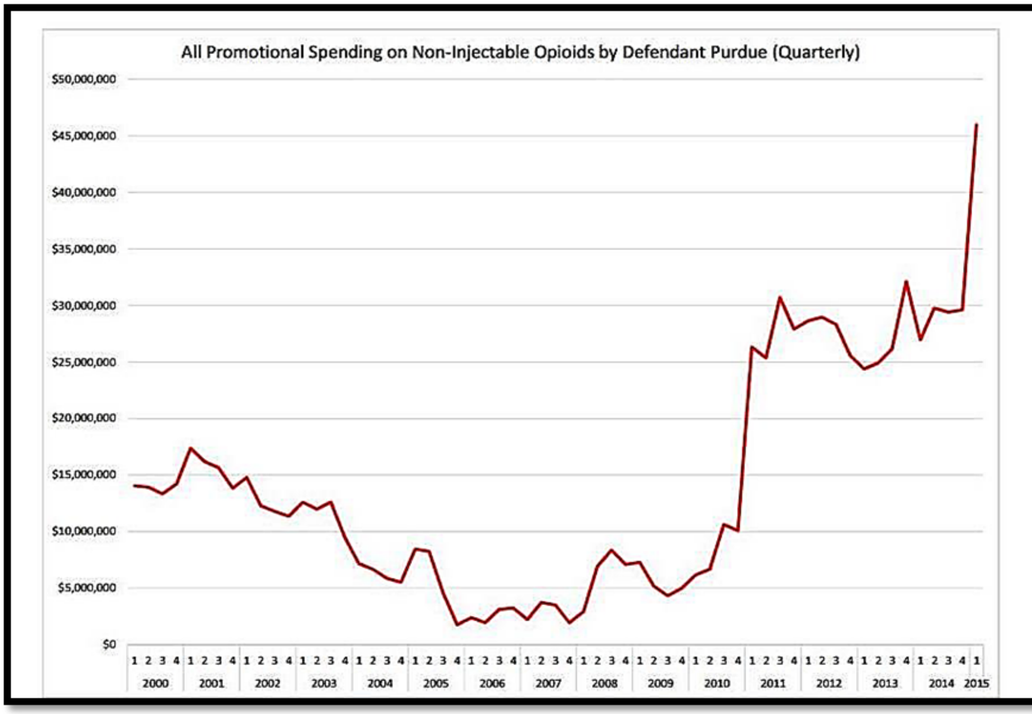

472. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):




473. Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



474. Purdue's quarterly spending notably decreased from 2000 to 2007—as Purdue came under investigation by the Department of Justice—but, as shown in the chart below, its spending increased dramatically after it settled with the DOJ in 2007, pleaded guilty to misleading doctors and patients about opioids, and paid a fine:




475. For its opioid, Actiq, Cephalon also engaged in direct marketing in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

476. Thousands of prescribers attended Cephalon speaking programs.

### *8. Manufacturer Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages*

477. In addition to making sales calls, Manufacturer defendants' sales representatives also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Manufacturer Defendants. These speaker programs and associated speaker trainings serve three purposes: they provide an incentive to doctors to prescribe,

or increase their prescriptions of, a particular drug; to qualify to be selected for a forum in which to further market to the speaker himself or herself; and an opportunity to market to the speaker's peers. The Manufacturer Defendants grade their speakers, and future opportunities are based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.

478. As detailed below, Insys paid prescribers for *fake* speakers' programs in exchange for prescribing its product, Subsys. Insys's schemes resulted in countless speakers' programs at which the designated speaker did not speak, and, on many occasions, speaker programs at which the only attendees at the events were the speaker and an Insys sales representative. It was a pay-to-prescribe program.

479. Insys used speakers' programs as a front to pay for prescriptions, and paid to push opioids onto patients who did not need them.

**C. The Manufacturer Defendants Targeted Vulnerable Populations**

480. The Manufacturer Defendants specifically targeted their marketing at two vulnerable populations—the elderly and veterans.

481. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression which occurs more frequently in elderly patients.

482. The Manufacturing Defendants promoted the notion—without adequate scientific foundation—that the elderly are particularly unlikely to become addicted to opioids. The AGS 2009 Guidelines, for example, which Purdue, Endo, and Janssen publicized, described the risk of addiction as "*exceedingly low* in older patients with no current or past history of substance abuse." (emphasis added). As another example, an Endo-sponsored CME put on by NIPC, *Persistent Pain*

*in the Older Adult*, taught that prescribing opioids to older patients carried "possibly less potential for abuse than in younger patients." Contrary to these assertions, however, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.

483. Similarly, Endo targeted marketing of Opana ER towards patients over 55 years old. Such documents show Endo treated Medicare part D patients among the "most valuable customer segments." However, in 2013, one pharmaceutical benefits management company recommended against the use of Opana ER for elderly patients and unequivocally concluded: "[f]or patients 65 and older these medications are not safe, so consult your doctor."

484. According to a study published in the 2013 *Journal of American Medicine*, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries. A 2008 survey showed that prescription drug misuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. Veterans are twice as likely as non-veterans to die from an opioid overdose.

485. Yet the Manufacturing Defendants deliberately targeted veterans with deceptive marketing. For example, a 2009 publication sponsored by Purdue, Endo, and Janssen, and distributed by APF with grants from Janssen and Endo, was written as a personal narrative of one veteran but was in fact another vehicle for opioid promotion. Called *Exit Wounds*, the publication describes opioids as "underused" and the "gold standard of pain medications" while failing to disclose significant risks of opioid use, including the risks of fatal interactions with benzodiazepines. According to a VA Office of Inspector General Report, 92.6% of veterans who

were prescribed opioid drugs were also prescribed benzodiazepines, despite the increased danger of respiratory depression from using the two drugs together.

486. Opioid prescriptions have dramatically increased for veterans and the elderly. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59. And in 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they did in 2001.

### D. Insys Employed Fraudulent, Illegal, and Misleading Marketing Schemes to Promote Subsys

487. Insys's opioid, Subsys, was approved by the FDA in 2012 for "management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Under FDA rules, Insys could only market Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl ("TIRF").

488. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a Risk Evaluation and Mitigation Strategy ("REMS") for Subsys and other TIRF products, such as Cephalon's Actiq and Fentora. The purpose of REMS was to educate "prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose" for this type of drug and to "ensure safe use and access to these drugs for patients who need them." Prescribers must enroll in the TIRF REMS before writing a prescription for Subsys.

489. Since its launch, Subsys has been an extremely expensive medication, and its price continues to rise each year. Depending on a patient's dose strength and frequency of use, a month's supply of Subsys could cost in the thousands of dollars.

490. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report ("Staff Report"), the prior authorization process includes "confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied …."

491. These prior authorization requirements proved to be daunting. Subsys received reimbursement approval in only approximately 30% of submitted claims. In order to increase approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center ("IRC"), to obtain approval for Subsys reimbursements. This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading information to insurers and payors regarding patients' diagnoses and medical conditions.

492. Subsys has proved to be extremely profitable for Insys. Insys made approximately $330 million in net revenue from Subsys in 2015. Between 2013 and 2016, the value of Insys stock rose 296%.

493. Since its launch in 2012, Insys aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics, including its reimbursement-related fraud. Through its sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence for such uses, and misrepresented the appropriateness of Subsys for treatment those

conditions. It implemented a kickback scheme wherein it paid prescribers for fake speakers' programs in exchange for prescribing Subsys. All of these fraudulent and misleading schemes had the effect of pushing Insys's dangerous opioid onto patients who did not need it.

494. Insys incentivized its sales force to engage in illegal and fraudulent conduct. Many of the Insys sales representatives were new to the pharmaceutical industry and their base salaries were low compared to industry standard. The compensation structure was heavily weighted toward commissions and rewarded reps more for selling higher (and more expensive) doses of Subsys, a "highly unusual" practice because most companies consider dosing a patient-specific decision that should be made by a doctor.

495. The Insys "speakers program" was perhaps its most widespread and damaging scheme. A former Insys salesman, Ray Furchak, alleged in a *qui tam* action that the sole purpose of the speakers program was "in the words of his then supervisor Alec Burlakoff, 'to get money in the doctor's pocket.'" Furchak went on to explain that "[t]he catch … was that doctors who increased the level of Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of 200 micrograms), would receive the invitations to the program—and the checks." It was a pay-to-prescribe program.

496. Insys's sham speaker program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Insys executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself.

497. In May of 2015, two Alabama pain specialists were arrested and charged with illegal prescription drug distribution, among other charges. The doctors were the top prescribers of Subsys, though neither were oncologists. According to prosecutors, the doctors received illegal kickbacks from Insys for prescribing Subsys. Both doctors had prescribed Subsys to treat neck,

back, and joint pain. In February of 2016, a former Insys sales manager pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to induce one of these doctors to prescribe Subsys. The plea agreement states that nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer patients. In May of 2017, one of the doctors was sentenced to 20 years in prison.

498. In June of 2015, a nurse practitioner in Connecticut described as the state's highest Medicare prescriber of narcotics, pled guilty to receiving $83,000 in kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. Insys paid the nurse as a speaker for more than 70 dinner programs at approximately $1,000 per event; however, she did not give any presentations. In her guilty plea, the nurse admitted receiving the speaker fees in exchange for writing prescriptions for Subsys.

499. In August of 2015, Insys settled a complaint brought by the Oregon Attorney General. In its complaint, the Oregon Department of Justice cited Insys for, among other things, misrepresenting to doctors that Subsys could be used to treat migraine, neck pain, back pain, and other uses for which Subsys is neither safe nor effective, and using speaking fees as kickbacks to incentivize doctors to prescribe Subsys.

500. In August of 2016, the State of Illinois sued Insys for similar deceptive and illegal practices. The Complaint alleged that Insys marketed Subsys to high-volume prescribers of opioid drugs instead of to oncologists whose patients experienced the breakthrough cancer pain for which the drug is indicated. The Illinois Complaint also details how Insys used its speaker program to pay high volume prescribers to prescribe Subsys. The speaker events took place at upscale restaurants in the Chicago area, and Illinois speakers received an "honorarium" ranging from $700 to $5,100, and they were allowed to order as much food and alcohol as they wanted. At most of

the events, the "speaker" being paid by Insys did not speak, and, on many occasions, the only attendees at the events were the speaker and an Insys sales representative.

501. In December of 2016, six Insys executives and managers were indicted and then, in October 2017, Insys's founder and owner was arrested and charged with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. A U.S. Department of Justice press release explained that, among other things: "Insys executives improperly influenced health care providers to prescribe a powerful opioid for patients who did not need it, and without complying with FDA requirements, thus putting patients at risk and contributing to the current opioid crisis." A Drug Enforcement Administration ("DEA") Special Agent in Charge further explained that: "Pharmaceutical companies whose products include controlled medications that can lead to addiction and overdose have a special obligation to operate in a trustworthy, transparent manner, because their customers' health and safety and, indeed, very lives depend on it."

## E. The Manufacturer Defendants' Scheme Succeeded, Creating a Public Health Epidemic

### *1. The Manufacturer Defendants dramatically expanded opioid prescribing and use*

502. The Manufacturer Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

503. Endo, for example directed the majority of its marketing budget to sales representatives—with good results: 84% of its prescriptions were from the doctors they detailed. Moreover, as of 2008, cancer and post-operative pain accounted for only 10% of Opana ER's uses;

virtually all of Endo's opioid sales—and profits—were from a market that did not exist ten years earlier. Internal emails from Endo staff attributed increases in Opana ER sales to the aggressiveness and persistence of sales representatives.

504. Cephalon also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated $15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists." Actiq became Cephalon's second best-selling drug. By the end of 2006, Actiq's sales had exceeded $500 million. Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."

505. Upon information and belief, each of the Manufacturer Defendants tracked the impact of their marketing efforts to measure their impact in changing doctors' perceptions and prescribing of their drugs. They purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. For instance, they monitored doctors' prescribing before and after detailing visits, and at various levels of detailing intensity, and before and after speaker programs. Defendants invested in their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances and more generally, Defendants' marketing changed prescribers' willingness to prescribe opioids, led them to prescribe more of their opioids, and persuaded them to continue prescribing opioids or to switch to supposedly "safer" opioids, such as ADF.

506. This success would have come as no surprise. Drug company marketing materially impacts doctors' prescribing behavior. The effects of sales calls on prescribers' behavior is well documented in the literature, including a 2017 study that found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers. The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study examined four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

507. Manufacturing Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain. These results are directly due to the Manufacturing Defendants' fraudulent marketing campaign focused on several misrepresentations.

508. Thus, both independent studies and Manufacturer Defendants' own behavior confirm that Defendants' marketing scheme dramatically increased their sales.

#### *2. Manufacturer Defendants' deception in expanding their market created and fueled the opioid epidemic*

509. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse." It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

510. There is a parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."

511. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

### V. DEFENDANTS THROUGHOUT THE SUPPLY CHAIN DELIBERATELY DISREGARDED THEIR DUTIES TO MAINTAIN EFFECTIVE CONTROLS AND TO IDENTIFY, REPORT, AND TAKE STEPS TO HALT SUSPICIOUS ORDERS

512. The Manufacturer Defendants created a vastly and dangerously larger market for opioids. They and the Distributor Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties.

513. Manufacturing Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Manufacturing Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

514. As the Manufacturer Defendants increased the demand for opioids, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

### A. Manufacturer Defendants and Distributor Defendants Have a Duty to Report Suspicious Orders and Not to Ship Those Orders Unless Due Diligence Disproves Their Suspicions

515. Multiple sources impose duties on the Defendants to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions.

516. First, under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding the market, including Plaintiff's

Community, with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm.

517. Second, each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion, to speak accurately and truthfully.

518. Third, each of the Manufacturer Defendants and Distributor Defendants was required to register with the DEA to manufacture and/or distribute Schedule II controlled substances. *See* 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100. As registrants, these Defendants were required to "maint[ain] … effective controls against diversion" and to "design and operate a system to disclose … suspicious orders of controlled substances." 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74. These Defendants were further required to take steps to halt suspicious orders. These Defendants violated their obligations under federal law.

519. Fourth, Defendants also breached duties under New York law. The Distributor Defendants operate within New York and Plaintiff's Community and distribute prescription opioid drugs to pharmacies and other health care providers.

520. At all relevant times, the Distributor Defendants purchased prescription opioid drugs from manufacturers, and sold them to pharmacies and other health care providers in New York and Plaintiff's Community.

521. The Distributor Defendants dominate 85% of the market share for the distribution of prescription opioids. Upon information and belief, most or nearly all of the prescription opioids that were sold to health care providers within New York and Plaintiff's Community were purchased from the Distributor Defendants.

522. Federal regulations require the Distributor Defendants to "design and operate a system to disclose . . . suspicious orders of controlled substances . . . Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

523. Under the relevant statutes, the Distributor Defendants are required to establish effective controls against suspicious orders to prevent prescription drugs from being diverted into the community, including:

a. Maintaining detailed records of narcotics sold to pharmacies and other retail and health care providers in order to identify and track suspicious orders;

b. Reporting suspicious orders of controlled substances, including prescription opioids, to alert regulatory and law enforcement officials when it appears that prescription drugs are being diverted for illegal use; and

c. Identifying suspicious orders, based on knowledge of the legal market for narcotics, and the Distributor Defendants' unique ability to conduct due diligence.

524. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market." Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion

through active participation by registrants within the drug delivery chain. All registrants – which includes all manufacturers and distributors of controlled substances—must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

525. The CSA requires manufacturers and distributors of Schedule II substances like opioids to: (a) limit sales within a quota set by the DEA for the overall production of Schedule II substances like opioids; (b) register to manufacture or distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; and (d) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

526. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs." When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the Department of Health and Human Services;

b. Total net disposal of the basic class of each drug by all manufacturers;

c. Trends in the national rate of disposal of the basic class of drug;

d. An applicant's production cycle and current inventory position;

e. Total actual or estimated inventories of the class of drug and of all substances manufactured from the class and trends in inventory accumulation; and

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.

527. It is unlawful to manufacture a controlled substance in Schedule II, like prescription opioids, in excess of a quota assigned to that class of controlled substances by the DEA.

528. To ensure that even drugs produced within quota are not diverted, federal regulations issued under the CSA mandate that all registrants, manufacturers and distributors alike, "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id*. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id*. Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."

529. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor or manufacturer need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

530. In sum, these Defendants have several responsibilities under state and federal law with respect to control of the supply chain of opioids. First, they must set up a system to prevent diversion, including excessive volume and other suspicious orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities. Further, they must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

531. State and federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent manufacturers and distributors would not fall. Together, these laws and industry guidelines make clear that Distributor Defendants and Manufacturer Defendants alike possess and are expected to possess specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled.

532. Further, these laws and industry guidelines make clear that the Distributor Defendants and Manufacturer Defendants alike have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

533. The FTC has recognized the unique role of distributors. Since their inception, Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, Distributor Defendants also offer their

pharmacy, or dispensing, customers a broad range of added services. For example, Distributor Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

534. Manufacturer Defendants also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from their purchase of data from commercial sources, such as IMS Health. Their extensive boots-on-the-ground through their sales force, allows the Manufacturer Defendants to observe the signs of suspicious prescribing and dispensing discussed elsewhere in this Complaint—lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. In addition, Manufacturer Defendants regularly mined data, including, upon information, chargeback data, which allowed them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusual high dose prescribing, which would have alerted them, independent of their sales representatives, to

suspicious prescribing. These information points gave Manufacturer Defendants insight into prescribing and dispensing conduct that enabled them to play a valuable role in preventing diversion and fulfilling their obligations under the CSA.

535. Defendants have a duty to be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

536. Defendants breached their duties by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids.

### B. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders

537. The reason for the reporting rules is to create a "closed" system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

538. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

539. Recently, Mallinckrodt, a prescription opioid manufacturer, admitted in a settlement with DEA that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA." Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."

540. Trade organizations to which Defendants belong have acknowledged that wholesale distributors have been responsible for reporting suspicious orders for more than 40 years. The Healthcare Distribution Alliance ("HDA"), formerly known as the Healthcare Distribution Management Association ("HDMA"), a trade association of pharmaceutical distributors to which Distributor Defendants belong, has long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society." Guidelines established by the HDA also explain that distributors, "[a]t the center of a sophisticated supply chain … are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."

541. The DEA also repeatedly reminded the Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and

customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Each of the Distributor Defendants attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

542. The DEA also advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they are "one of the key components of the distribution chain. If the closed system is to function properly … distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as … the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people." The DEA's September 27, 2006 letter also expressly reminded them that registrants, in addition to reporting suspicious orders, have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The same letter reminds distributors of the importance of their obligation to "be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes," and warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

543. The DEA sent another letter to Defendants on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion"

and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."

### C. Defendants Worked Together to Inflate the Quotas of Opioids They Could Distribute

544. Finding it impossible to legally achieve their ever-increasing sales ambitions Defendants engaged in the common purpose of increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids.

545. Wholesale distributors such as the Distributor Defendants had close financial relationships with both Manufacturing Defendants and customers, for whom they provide a broad range of value-added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For example, wholesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock. Through their generic source programs, wholesalers are also able to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers. Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

546. Distributor Defendants had financial incentives from the Manufacturing Defendants to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

547. The Manufacturing Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The *Washington Post* has described the practice as industry-wide, and the HDA includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt, a prescription opioid manufacturer, acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants," meaning pharmacies or other dispensaries, such as hospitals. Manufacturing Defendants buy data from pharmacies as well. This exchange of information, upon information, and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

548. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. The manufacturers negotiated agreements

whereby the Manufacturing Defendants installed security vaults for the Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

549. In addition, Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum ("PCF") and the HDA.

550. The Pain Care Forum ("PCF") has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

551. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse." Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.

552. The Defendants who stood to profit from expanded prescription opioid use are members of and/or participants in the PCF. In 2012, membership and participating organizations included Endo, Purdue, Actavis and Cephalon. Each of the Manufacturing Defendants worked together through the PCF. But, the Manufacturing Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA. For example, the Executive Committee of the HDA currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group

President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. The Distributor Defendants participated directly in the PCF as well.

553. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturing Defendants including Actavis, Endo, Purdue, Mallinckrodt and Cephalon were members of the HDA. Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturing Defendants by advocating for the many benefits of members, including "strengthen[ing] … alliances."

554. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections." Clearly, the HDA and the Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and "alliances" between the Marketing and Distributor Defendants.

555. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other's businesses. For example, the manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

556. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their "most recent year end net sales" through wholesale distributors, including the Distributor Defendants AmerisourceBergen, Cardinal Health, and McKesson and their subsidiaries.

557. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Marketing and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

558. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturing Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers … to hold strategic business discussions on the most pressing industry issues." The conferences also gave the Marketing and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry." The HDA and its conferences were significant opportunities for the Manufacturing and Distributor Defendants to interact at a high-level of leadership. It is clear that the Manufacturing Defendants embraced this opportunity by attending and sponsoring these events.

559. After becoming members of HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributor and manufacturer members.

c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributor and manufacturer members.

d. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

e. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.

560. The Distributor Defendants and Manufacturing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information

regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers…" The Manufacturing Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell prescription opioids.

561. Taken together, the interaction and length of the relationships between and among the Manufacturing and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

562. The HDA and the PCF are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation.

563. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (the "Industry Compliance Guidelines") regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.

564. This statement by the HDA and the Industry Compliance Guidelines show that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Here, it is apparent that all of the Defendants found the same balance—an overwhelming pattern and practice of failing to identify, report, or halt suspicious orders and to prevent diversion.

565. The Defendants' scheme had a decision-making structure driven by the Manufacturing Defendants and corroborated by the Distributor Defendants. The Manufacturing Defendants worked together to control the state and federal government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and identify suspicious orders and report them to the DEA.

566. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Manufacturing and Distributor Defendants did this through their participation in the PCF and HDA.

567. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

568. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with their reporting obligations.

569. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

570. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flood of opioids continued unimpeded.

### D. Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers

571. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Defendants but has not been disclosed to the public.

572. Publicly available information confirms that Distributor and Manufacturing Defendants funneled far more opioids into communities across the United States than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to Distributor and Manufacturing Defendants, would have alerted them to potentially suspicious orders of opioids.

573. This information includes the following facts:

a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy

and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

c. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion, as described herein. ;

d. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and

e. Manufacturing Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

574. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain.

575. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters

Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the "Data Vendors").

576. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids. The "know your customer" questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

577. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.

578. IMS Health, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.

579. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.

580. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.

581. Defendants were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities.

582. Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012 and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include seventy-six actions involving orders to show cause and forty-one actions involving immediate suspension orders, all for failure to report suspicious orders.

583. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

> Actions have consequences—so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

584. Moreover, Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one

example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."

585. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]" She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report." This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

586. A Kadian prescriber guide discusses abuse potential of Kadian. It is full of disclaimers that Actavis has not done any studies on the topic and that the guide is "only intended to assist you in forming your own conclusion." However, the guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) "KADIAN may be less

likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." (p. 1-2). The guide is copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma.

587. Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers, but not to report them, to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement, nor to report those doctors who drove Defendants' sales.

588. Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors' sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

589. For example, at a national sales meeting presentation in 2011, Actavis pressed its sales representatives to focus on its high prescribers: "To meet and exceed our quota, we must continue to get Kadian scripts from our loyalists. MCOs will continue to manage the pain products more closely. We MUST have new patient starts or we will fall back into 'the big leak'. We need to fill the bucket faster than it leaks." "The selling message should reflect the opportunity and prescribing preferences of each account. High Kadian Writers / Protect and Grow/ Grow = New Patient Starts and Conversions." (pg 13). In an example of how new patients + a high volume physician can impact performance: "102% of quota was achieved by just one high volume physician initiating Kadian on 2-3 new patients per week."

590. This focus on marketing to the highest prescribers had significant impact. It demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids and instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

591. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Manufacturing Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."

592. But given the closeness with which Defendants monitored prescribing patterns through IMS Health data, it is highly improbable that they were "fooled." In fact, a local pharmacist had noticed the volume of prescriptions coming from Dr. Paolino's clinic and alerted authorities. Purdue had the prescribing data from the clinic but alerted no one. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

593. As discussed below, Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company's policies or duties to report suspicious activity, and Endo

paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

594. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Manufacturer Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

### E. Manufacturer Defendants and Distributor Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion

595. As discussed above, Manufacturer Defendants and Distributor Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into communities across America. Despite the notice described above, and in disregard of their duties, these Defendants continued to pump massive quantities of opioids despite their obligations to control the supply, prevent diversion, report and take steps to halt suspicious orders.

596. Governmental agencies and regulators have confirmed (and in some cases Defendants have admitted) that Defendants did not meet their obligations and have uncovered especially blatant wrongdoing.

597. For example, on January 5, 2017, McKesson entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million civil penalty for, inter alia, failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders

placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." Upon information and belief, McKesson engaged in similar wrongful activity in New York. McKesson further admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers" including the McKesson Distribution Center located in Washington Court House, Ohio. Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from certain of its facilities some of which (including the one in Washington Court House, Ohio), investigators found "were supplying pharmacies that sold to criminal drug rings."

598. Similarly, in 2017, the Department of Justice fined Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances—orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders." Upon information and belief, Mallinckrodt engaged in similar wrongful activity in New York.

599. On December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the Controlled Substances Act in Maryland, Florida and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the

DEA. In the settlement agreement, Cardinal Health admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

a. "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)";

b. "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)"; and

c. "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

600. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities alone are sufficient to show that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for $16 million to the state; Cardinal Health settled for $20 million.

601. Upon information and belief, Cardinal Health and AmerisourceBergen engaged in similar wrongful activity in New York.

602. H.D. Smith has also routinely been found to have violated its duties to report suspicious orders and halt suspicious shipments of prescription opioids. According to a recent letter from the U.S. House of Representatives Committee on Energy and Commerce, data provided to the Committee showed that between 2007 and 2008, H.D. Smith provided two pharmacies in Williamson, WV, a town with a population of 3,191, a combined total of nearly 5 million hydrocodone and oxycodone pills—approximately 1,565 hydrocodone and oxycodone pills for every man, woman, and child in Williamson, WV. According to press reports, H.D. Smith distributed approximately 13.7 million hydrocodone and 4.4 million oxycodone pills to West Virginia between 2007 and 2012. Press accounts further indicate that H.D. Smith did not submit any suspicious order reports to the state for at least a decade. Upon information and belief, H.D. Smith engaged in similar wrongful activities in Plaintiff's Community and among its members.

603. Similarly, Miami-Luken has come under DEA scrutiny for facilitating the diversion of significant quantities of the highly addictive pain killers, oxycodone and hydrocodone. On November 23, 2015, the DEA issued an Order to Show Cause against Miami-Luken to begin the process of revoking Miami-Luken's registration to distribute controlled substances under the Controlled Substances Act. In early 2016, Miami-Luken agreed to pay the state of West Virginia $2.5 million to resolve allegations that the company knowingly shipped opioids to West Virginia pharmacies without exercising sufficient monitoring or control.

604. According to a recent letter from the U.S. House of Representatives Committee on Energy and Commerce, data provided to the Committee showed that from 2008 to 2015 Miami-Luken provided one pharmacy in Oceana, WV, 4,391,520 hydrocodone and oxycodone pills. Oceana, WV's population was a mere 1,394 in 2010. As the Committee noted, this means that in 2014 alone, Miami-Luken provided roughly 689 pills for every man, woman, and child in Oceana.

Similarly, according to the data Miami-Luken provided to the Committee, in 2008, Miami-Luken provided two pharmacies in Kermit, WV, 2,283,700 hydrocodone and oxycodone pills—5,624 pills for every man, woman, and child in Kermit, WV. Upon information and belief, Miami-Luken engaged in similar wrongful activity in New York.

605. Thus, it is the various governmental agencies who have alleged or found—and the Defendants themselves who have admitted—that the Defendants, acting in disregard of their duties, pumped massive quantities of opioids into communities around the country despite their obligations to control the supply, prevent diversions, and report and take steps to halt suspicious orders.

**F. The National Retail Pharmacies Were on Notice of and Contributed to Illegal Diversion of Prescription Opioids**

606. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids. They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

607. Each of the National Retail Pharmacies does substantial business throughout the United States. This business includes the distribution and dispensing of prescription opioids.

608. The National Retail Pharmacies distributed and dispensed substantial quantities of prescription opioids in Plaintiff's Community. In addition, they distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to New York. The National Retail Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it, and contributed substantially to the diversion problem.

609. The National Retail Pharmacies developed and maintained extensive data on opioids they distributed and dispensed. Through this data, National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in New York in particular. They used the data to evaluate their own sales activities and workforce. Upon information and belief, the National Retail Pharmacies also provided manufacturing and distributing Defendants with data regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a valuable resource that they could have used to help stop diversion, but failed to do so.

### *1. The National Retail Pharmacies Have a Duty to Prevent Diversion*

610. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

611. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." See 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

612. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

613. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

614. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

615. Suspicious pharmacy orders are red flags for, if not direct evidence of, diversion.

616. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

617. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

618. Despite their legal obligations as registrants under the CSA, the National Retail Pharmacies allowed widespread diversion to occur—and they did so knowingly.

619. Performance metrics and prescription quotas adopted by the National Retail Pharmacies for their retail stores contributed to their failure. Under CVS's Metrics System, for example, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of National Retail Pharmacies and into communities throughout the country. The policies remained in place even as the epidemic raged.

620. The performance metric systems rate the pharmacist employees at the stores operated by Retail Chain Pharmacies based solely on productivity. These requirements place significant and unrealistic time pressures on the pharmacists.

621. The Retail Chain Pharmacies measure how many and how quickly prescriptions are filled daily based on store volume. Many of the Retail Chain Pharmacies' locations require pharmacists to fill one prescription every three minutes. The programs may also measure how many telephone calls are made to customers to refill and/or pick up prescriptions; how many flu shots are given; as well as other pharmacy tasks. All measurements focus on productivity with the end goal of maximizing retail Defendants' profits.

622. In addition to the pharmacist's other duties, Retail Chain Pharmacies required their employee pharmacists to fill more than 600 prescriptions per work shift.

623. For example, CVS maintains a "Metrics System" to evaluate performance in its pharmacists. Under CVS's Metrics System, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists

are calculated, in part, on how many prescriptions that pharmacist fills within a year. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions pharmacists are able to fill within a year.

624. At the same time that Retail Chain Pharmacies increased demands for productivity, they cut the hours of pharmacy technicians, leaving pharmacists severely understaffed and unable to provide all necessary services.

625. Retail Chain Pharmacies' high-volume and increased-profits business model led to a greater number of errors in dispensing prescriptions, which can result in substantial harm to pharmacy customers.

626. A survey conducted by the Institute for Safe Medication Practices ("ISMP") of 673 pharmacists revealed that 83% believed that distractions due to performance metrics or measured wait times contributed to dispensing errors, and that 49% felt specific time measurements were a significant contributing factor.

627. Further, the National Association of Boards of Pharmacy found that performance metrics, which measure the speed and efficiency of prescription work flow—using such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift—may distract pharmacists and impair professional judgment.

628. The practices of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions at a pharmacy.

629. The Retail Chain Pharmacies productivity policies are directly at odds with their performance of due diligence obligations required to be performed in conjunction with federal and state law, especially given the higher duty of care associated with the prescription of narcotic opioids.

630. The Retail Chain Pharmacies were negligent in failing to ensure, or even permit, pharmacists in their stores to exercise the reasonable care necessary under the circumstances to detect and prevent diversion.

631. Upon information and belief, this problem was compounded by the National Retail Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

632. Upon information and belief, the National Retail Pharmacies also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

633. Upon information and belief, the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions

that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

634. Upon information and belief, the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

635. Upon information and belief, the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

636. The National Retail Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

***2. Multiple Enforcement Actions against the National Retail Pharmacies Confirms their Compliance Failures.***

637. The National Retail Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacies.

a. CVS

638. CVS is one of the largest companies in the world, with annual revenue of more than $150 billion. According to news reports, it manages medications for nearly 90 million customers

at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

639. CVS is a repeat offender and recidivist: the company has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the United States Department of Justice ("DOJ"). It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

640. As recently as July 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.

641. This fine was preceded by numerous others throughout the country.

642. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.

643. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.

644. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

645. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.

646. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.

647. In May 2015, CVS agreed to pay a $22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."

648. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.

649. In August 2013, CVS was fined $350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.

650. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.

b. Walgreens

651. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

652. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales.

653. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

654. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.

655. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens' suggested, in reviewing the legitimacy of

prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.

656. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.

657. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).

658. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

659. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite the

context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.

c. Rite Aid

660. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States, with annual revenue of more than $21 billion.

661. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined $5 million in civil penalties for its violations of the CSA.

662. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b).

663. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from National Retail Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

664. The litany of state and federal actions against the National Retail Pharmacies demonstrate that they routinely, and as a matter of standard operating procedure, violated their legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

665. Throughout the country and in New York in particular, the National Retail Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

666. Upon information and belief, from the catbird seat of their retail pharmacy operations, the National Retail Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into New Yorkand the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

667. Upon information and belief, the National Retail Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

668. Upon information and belief, because of (among others sources of information) regulatory and other actions taken against the National Retail Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the National Retail Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

669. The National Retail Pharmacies' actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

### G. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

670. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action—or may not know to take action at all.

671. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017, McKesson paid $150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

672. More generally, the Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves

everyone." Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria." Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

673. Along the same lines, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion. Defendant McKesson has also publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

674. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances." A company spokeswoman also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."

675. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

676. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

677. Defendant Mallinckrodt similarly claims to be "committed … to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances …."

678. Other Manufacturing Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."

679. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue's recent pronouncements in response to opioid abuse.

680. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create …. That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse …." Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with … communities, law enforcement, and government." And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion." Contrary to its public statements, Purdue worked behind the scenes to push back against law enforcement.

681. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

682. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due

diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

## VI. THE PURDUE-RELATED ADDITIONAL DEFENDANTS PARTICIPATED IN AND PROFITED FROM PURDUE'S WRONGDOING

### A. Structure of the Purdue Entities and the Roles of the Purdue-Related Additional Defendants

683. At all relevant times, the Sackler Families – in particular, as detailed below, Richard Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Kathe Sackler, Beverly Sackler, Theresa Sackler, Ilene Sackler Lefcourt, David Sackler, and Raymond Sackler Trust ("Sackler Defendants") – controlled Purdue and its associated companies. Purdue is part of a complex web of entities which the Sackler Families own and control. PPI is the managing general partner of PPLP and of many of the various Purdue-related entities. Its status as managing general partner of the various entities ensures PPI's control of those entities. In turn, at all relevant times, all of the members of the board of PPI have been members of the Sackler Families or Sackler-family retainers.

684. Because the Sackler Families control of the board of PPI, the officers of PPI and PPLP reported to them. This ensured Sackler control of PPI and PPLP, even when the officers of those entities were not themselves members of the Sackler Families.

685. At relevant times, Rhodes Tech or its predecessor has manufactured and supplied PPLP with oxycodone, the active pharmaceutical ingredient in OxyContin, for use in the manufacture of pharmaceutical preparations.

686. At relevant times, Rhodes Tech Inc. has manufactured and supplied PPLP with oxycodone, the active pharmaceutical ingredient in OxyContin, for use in the manufacture of pharmaceutical preparations or has managed Rhodes Tech or its predecessor in doing so.

687. At all relevant times, Rhodes Pharma has marketed a generic form of OxyContin which is manufactured by Purdue Pharmaceuticals L.P. (“PPNC”), a Delaware limited partnership, which is a subsidiary of PPLP and which owns and operates a pharmaceutical manufacturing facility in Wilson, North Carolina.

688. At all relevant times, Rhodes Pharma Inc. has marketed a generic form of OxyContin which is manufactured by PPNC.

689. At relevant times, PF Labs engaged in the business of manufacturing OxyContin for PPLP.

690. The Sackler Defendants made the decision that the Sackler Families should enter the generic market for OxyContin in or about 2008 and that it should do so through Rhodes Pharma, a Sackler-owned entity created for that purpose.

691. The Sackler Defendants caused Purdue and other associated companies that they beneficially owned and controlled to distribute to the Sackler Families hundreds of millions of dollars of profits earned by Purdue and its associated companies from the sale of opioids.

692. Each of the Sackler Defendants named herein has served on the board of directors of, or as an officer of, Purdue and one or more Purdue-related entities.

693. The Sackler Defendants beneficially own and control all of the entities owned by the Sackler Families, including PF Labs and the Rhodes Defendants, in substantially the same way as they control PPLP and its affiliates, although they may do so using different holding companies and trusts than those used to control PPLP. The Purdue-related entities that are not controlled by the Sackler Defendants through PPI are controlled by them through different entities unknown to Plaintiff.

694. At all relevant times, Richard Sackler played an active and central role in the management of Purdue and the Purdue-related Defendants. He began working for Purdue as Assistant to the President (his father, Raymond) in the 1970s. He later served as Vice President of Marketing and Sales. In the early 1990s he became Senior Vice President, which was the position he held at the time OxyContin was launched in 1996. In 1999, he became President, and he served in that position until 2003.

695. Richard Sackler resigned as President in 2003, apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, he continued to serve, with his uncle Mortimer, as Co-Chair of the Board of Purdue. In that way, among others, the family maintained control over their family-owned business, even though they were no longer officers, because the officers reported to them.

696. As a senior executive of Purdue, Richard Sackler was actively involved in the invention, development, marketing, promotion, and sale of Purdue's opioid products, including OxyContin. He worked tirelessly to make OxyContin a blockbuster, telling colleagues how devoted he was to the drug's success. Along with his father (Raymond) and his uncle (Mortimer), he launched OxyContin with one of the biggest pharmaceutical marketing campaigns in history, deploying many persuasive techniques pioneered by his uncle Arthur. Within five years of its introduction, OxyContin was generating a billion dollars a year. When OxyContin met with resistance, Richard participated in Purdue's efforts to counter that resistance.

697. At all relevant times, Richard Sackler served as a trustee of one or more trusts that beneficially own and control Purdue.

698. Richard Sackler is the direct or indirect beneficiary of some portion of 25% of the profits earned by Purdue and its affiliates from the sale of opioids.

699. Jonathan Sackler was a Vice President of Purdue in 1991, and by 2000 he was a Senior Vice President. Like his brother Richard, he resigned that position in or after 2003, apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, he continued to serve on the board of Purdue.

700. At all relevant times, Jonathan Sackler served as a trustee of one or more trusts that beneficially own and control Purdue.

701. Jonathan Sackler is the direct or indirect beneficiary of some portion of 25% of the profits earned by Purdue and its affiliates from the sale of opioids.

702. Mortimer D.A. Sackler served as a Vice President of Purdue during the period of the development, launch, and promotion of OxyContin. He resigned that position in or after 2003, apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, he continued to serve on the Board of Purdue.

703. Mortimer D.A. Sackler is the direct or indirect beneficiary of 7.14% of the profits earned by Purdue and its affiliates from the sale of opioids.

704. Kathe A. Sackler was a Vice President of Purdue in 1991, and by 2000 she was a Senior Vice President. She resigned that position in or about 2003 due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, she continued to serve on the Board of Purdue.

705. Kathe A. Sackler is the direct or indirect beneficiary of 7.14% of the profits earned by Purdue and its affiliates from the sale of opioids.

706. Ilene Sackler Lefcourt served as Vice President of Purdue during the period of the development, launch, and promotion of OxyContin. She resigned that position in or after 2003,

apparently due to a concern that executive officers of Purdue would be held personally liable for opioid-related liabilities and crimes. However, she continued to serve on the Board of Purdue.

707. Ilene Sackler Lefcourt is the direct or indirect beneficiary of 7.14% of the profits earned by Purdue and its affiliates from the sale of opioids.

708. At all relevant times, Beverly Sackler served as a trustee of one or more trusts that beneficially own and control Purdue and to which 50% of the profits of Purdue and its affiliates from the sale of opioids has been conveyed. She has also served as a member of the board of directors of Purdue since the 1990s.

709. Beverly Sackler is the direct or indirect beneficiary of some portion of 50% of the profits earned by Purdue and its affiliates from the sale of opioids.

710. Theresa Sackler is the direct or indirect beneficiary of some portion of 50% of the profits earned by Purdue and its affiliates from the sale of opioids. She has also served as a member of the board of directors of Purdue since the 1990s.

711. David A. Sackler is the direct or indirect beneficiary of some portion of 25% of the profits earned by Purdue and its affiliates from the sale of opioids. He has also served as a member of the board of directors of Purdue since 2012.

712. Stuart Baker joined Purdue in 1994 as Executive Vice President of PPLP and as Vice President of PF Co. He served as legal counsel to the entire Purdue organization and the Sackler Families. He also served as an officer of other Sackler-owned, Purdue-related entities. He served as a trustee of one or more trusts that beneficially own and control Purdue and its affiliates. He served as Corporate Secretary for Purdue, and as such he gained direct knowledge of the wrongdoing alleged in the Complaint. In his capacity as an officer, director, and lawyer, he knowingly aided, abetted, participated in, and benefitted from the wrongdoing of Purdue as alleged

in the Complaint and knowingly aided and abetted the Sackler Families, and the Purdue-Related Additional Defendants, to structure their personal affairs and the personal and business organizations they beneficially owned and controlled in such a way as to attempt to evade personal liability for the wrongdoing in which he knew they had engaged and in which he knew they intended to continue to engage.

713. The Sackler Families are the sole beneficial owners of Purdue and its associated companies. All of Purdue’s and its associated companies’ profits go to Sackler-family trusts and entities.

**B. Purdue’s Directors Knowingly Participated in Purdue’s Wrongdoing**

714. The members of the board of Purdue were intimately involved in the activities of the entities that they managed, often on a weekly or even daily basis.

715. Purdue and the Sackler Families launched OxyContin with one of the biggest pharmaceutical marketing campaigns in history, deploying many persuasive techniques pioneered by Arthur Sackler. They trained and armed a force of approximately 1,000 sales representatives with charts showing OxyContin's purported benefits. A major thrust of the sales campaign was that OxyContin should be prescribed not merely for the kind of severe short-term pain associated with surgery or for cancer pain but also for less acute, longer-lasting pain, such as arthritis, back pain, sports injuries, and fibromyalgia among others. The number of conditions that OxyContin could treat seemed almost unlimited.

716. The training included "training in 'overcoming objections' from clinicians." "If a doctor inquired about addiction," the representative was instructed to respond thus: "'The delivery system is believed to reduce the abuse liability of the drug.'" Another sales representative said that Purdue executives "told us to say things like it is 'virtually' non-addicting."

717. Purdue sales representatives were provided with studies and literature provided by other physicians. Purdue had a speakers' bureau through which it paid several thousand doctors to attend medical conferences and deliver presentations about OxyContin's merits. Doctors were offered all-expenses-paid trips to pain-management seminars in places like Boca Raton. Doctors who attended these seminars wrote OxyContin prescriptions more than twice as often as those who did not.

718. Purdue also advertised in medical journals and produced promotional videos featuring not just satisfied patients but also doctor's testimonials. The marketing of OxyContin relied on an empirical circularity: the company convinced doctors of the drug's safety with literature that had been produced by doctors who were paid, or funded, by the company.

719. According to a former OxyContin sales representative, Richard Sackler was "'the dude that made it happen.'" Richard Sackler himself was tireless in his dedication to OxyContin's success. When benefit plans began citing OxyContin abuse as an excuse not to pay, Richard Sackler sent an email to sales representatives stating that, for insurers, "'addiction' may be a convenient way to just say 'NO.'"

720. Members of the Sackler family were daily on site at Purdue's headquarters, controlling the management of their family-owned business and all of its employees.

721. Richard Sackler is named as inventor on some 50 patents relating to oxycodone and other pain medications, including several patents apparently issued as late as 2016. Virtually all such patents invented by Richard Sackler were assigned to Purdue.

722. In 1997, both Richard and Kathe Sackler were part of a conspiracy to deceive physicians into believing that oxycodone was half as strong as morphine, when in fact the opposite

was true; this deception was known by Purdue to ease the fears of well-meaning and careful physicians about prescribing OxyContin for non-cancer pain uses.

723. In the late 1990s Richard, Jonathan and Kathe Sackler participated in an unlawful attempt to deceive European drug regulators into classifying OxyContin as totally uncontrolled, i.e., capable of being obtained without a prescription, despite the fact that all of these family members were by then well aware of the abuse liability of the drug in the U.S.

724. In 2001, Kathe Sackler attended a talk given by the chief medical officer of Sikorsky Aircraft, in which the speaker expressed grave concern about the risks associated with OxyContin; instead of acknowledging this fact to the medical officer, Kathe Sackler instead remained silent and returned to the Purdue headquarters, where employees were directed to find ways to undercut and deflect the Sikorsky medical officer's concerns.

725. In the period around 1999-2003, Purdue developed a method to cause company emails to self-destruct at a pre-determined time; this was an attempt to create a system where potentially incriminating documents would automatically self-destruct, even after receipt by unrelated third-parties. Richard, Jonathan and Kathe Sackler all were directly aware and supportive of this project.

### C. Members of the Sackler Families Were Aware of Risks Associated With OxyContin No Later Than the Summer of 1999

726. That prescription opioids would lead to addiction, and specifically that OxyContin could be, and was being, abused has been known to Purdue and to the members of the Sackler Families involved in running the family business since at least the summer of 1999.

727. In the summer of 1999, a Purdue sales representative wrote to the President of Purdue reporting widespread abuse of OxyContin. As a result of that memo, a secretary at Purdue,

Maureen Sara, was tasked with doing research on the Internet to learn about the nature and scope of the abuse, specifically to learn about how recreational drug users were misusing OxyContin.

728. In order to carry out her assignment, Ms. Sara began visiting drug-user Internet "news groups" or "chat rooms" on a daily basis. Two groups in particular that Ms. Sara visited were alt.drugs and alt.drugs.hard. For a period of time, in the late summer and early fall of 1999, Ms. Sara would forward screen shots from these news groups on a daily basis to Howard Udell, then General Counsel of Purdue.

729. In October or November, 1999, Ms. Sara prepared a memo summarizing her research into misuse of OxyContin. The memo described how users would remove the coating on the OxyContin pills, crush them, cook them, and snort or shoot them. Ms. Sara sent the memo containing the details of OxyContin abuse by drug users not only to the President of Purdue and to its General Counsel, but also to Purdue's then-medical director, and directly to members of the Sackler Families involved in the management of the company, including Richard Sackler, Jonathan Sackler, and Kathe Sackler.

730. Purdue, Richard Sackler, Jonathan Sackler, and Kathe Sackler were thus all aware of the risk and abuse potential and reality of OxyContin long before Purdue acknowledged the same to government, the healthcare community or the public. In sworn testimony before the U.S. House of Representatives in 2001, Purdue President Michael Friedman, in the presence of Purdue General Counsel Howard R. Udell, swore that the first the companies knew of widespread abuse of OxyContin was in the year 2000. This was, of course, patently inconsistent with what the members of the Sackler Families knew from the Sara memo they had received in 1999. No member of the Sackler Families at any time tried to correct the false narrative promulgated far and

wide about the abuse liability of OxyContin, nor corrected the false statement about when Purdue became aware of this problem with the drug.

731. Richard Sackler, Kathe Sackler, Jonathan Sackler, Theresa Sackler, Mortimer D.A. Sackler, and Ilene Sackler have been aware since at least 1999 of potential liability for Purdue and those acting in concert with Purdue. With the intention of shielding from creditors the proceeds of their wrongdoing, they have stripped out of Purdue and the Purdue-related Additional Defendants each and every year hundreds of millions of dollars of profits from the sales of OxyContin and other opioid-containing medications, including a generic form of OxyContin sold by Rhodes Pharma. All such transfers were and are fraudulent within the meaning of applicable fraudulent transfer statutes and case law; all such transfers unjustly enriched the recipients; and all such transferred funds should be clawed back from the Sackler Defendants in order to satisfy the opioid-related liabilities of the companies from which they were transferred.

### D. The Purdue-Related Defendants Continued to Oversee Purdue's Wrongdoing Even after Purdue Was Fined and Warned about Its Conduct

732. From 2001 to 2007, Purdue was investigated by 26 states and the U.S. Department of Justice. Beginning in or about 2003, advised by Baker, who served as legal counsel to the entire Purdue organization and the Sackler Families, all of the Sacklers who served as executive officers of Purdue resigned out of concern that they might be held personally liable for conduct on behalf of Purdue in which they had previously engaged and in which they expected and intended to continue to engage after their respective resignations.

733. In 2007, PF Co. agreed to pay nearly $700 million and pleaded guilty to a felony for misleading doctors and patients about opioids. Purdue admitted that its supervisors and employees, "with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal

than other pain medications." At the same time, Purdue executive officers Michael Friedman (the CEO), Howard Udell (Vice President and General Counsel), and Paul Goldenheim (Chief Medical Officer) pleaded guilty to criminal charges that they let Purdue deceive doctors and patients about its opioids.

734. As part of the plea agreement in 2007, Purdue agreed to a detailed Corporate Integrity Agreement with the U.S. government. The Agreement required Purdue to appoint a Compliance Officer who would "be a member of senior management of Purdue," "make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors," and "be authorized to report on such matters to the Board of Directors at any time." The Corporate Integrity Agreement was built on the idea that the directors would ensure that Purdue never deceived doctors and patients again.

735. The Corporate Integrity Agreement included the directors as "Covered Persons" from 2007 through 2012. All Covered Persons, including the directors and CEO, were required to comply with rules that prohibit deception about Purdue opioids. The directors were required to undergo hours of training to ensure that they understood the rules. The directors were required to report all violations of the rules. The directors were warned that they could face consequences if they failed to comply with the rules. The directors certified that they had read and understood the rules and would comply with them.

736. The directors were aware of their obligations under the Corporate Integrity Agreement because in 2009 Purdue had to report to the Inspector General of the U.S. Department of Health and Human Services that it had not immediately trained a new director on the Agreement. Purdue reported: "a new Director was appointed to Purdue's Board of Directors, without timely notice to either Corporate Compliance or the Office of General Counsel, as otherwise required by

policy, resulting in failure to timely launch the training assignment to this new Board member." Purdue assured the U.S. government that it had trained the new director: "Relevant personnel were reminded of existing policy to notify Corporate Compliance and the Office of General Counsel of changes to the Board of Directors. In both instances, these individuals completed their training assignments within 1 day of Corporate Compliance learning of this issue." Purdue promised the government that the director's training had addressed "the proper methods of promoting, marketing, selling, and disseminating information about Purdue's products," so Purdue would never deceive doctors and patients again.

737. Every year since the 2007 guilty plea and Corporate Integrity Agreement, Purdue's directors received warning signs about Purdue's ongoing misconduct and opportunities to stop it.

738. In 2008, more Americans died from opioid overdoses than ever before.

739. In 2009, the *American Journal of Public Health* published an article about Purdue's opioid marketing entitled, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy." The article detailed Purdue's use of sales representatives, targeting of high-prescribers, and deception about addiction. That same year, CDC reported that deaths from opioids had recently tripled.

740. In 2010, *Time* magazine published a story about Purdue's opioids entitled, "The New Drug Crisis: Addiction by Prescription." Overdoses were the leading cause of accidental death in 15 states. By the spring of 2010, Purdue's directors had been told that Purdue could not get product liability insurance to cover OxyContin.

741. In 2011, the White House announced that prescription drug abuse was the nation's fastest-growing drug problem and called for "educating healthcare providers about prescription drug abuse … so they will not over-prescribe[.]" The CDC announced that prescription opioid

overdoses had reached epidemic levels and called out Purdue's opioids by name. That same year, *Fortune* magazine interviewed Purdue executives, including Vice President Alan Must. *Fortune* published a story about Purdue, the Sackler Families, and evidence that they profited from opioid addiction. Mr. Must admitted that Purdue was "well aware" of concerns about its conduct: "We are well aware of detractors. For those individuals who think we're evil … I don't think there's anything we can do that is going to change their opinion."

742. In 2012, the U.S. Senate launched an investigation into whether Purdue was deceiving doctors and patients about opioids. In a letter to the CEO of Purdue, the Senators warned of "an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers." The Senate letter warned Purdue specifically of the danger of patients taking higher doses: "over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks while data suggest that hundreds of thousands of patients nationwide may be on potentially dangerous doses." The Senate letter also warned about Purdue misleading doctors and patients: "There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting misleading information about the drugs' safety and effectiveness." The Senate put the directors on notice that they were under scrutiny, demanding that Purdue produce to investigators a set of "presentations, reports, and communications to Purdue's management team or board of directors from 2007 to the present."

743. In 2013, the *Los Angeles Times* revealed that Purdue had been compiling a list for the past decade of 1,800 doctors suspected of recklessly prescribing its opioids, but Purdue had reported only 8% of them to authorities. Purdue attorney Robin Abrams gave multiple interviews to the newspaper. Abrams was a Vice President of Purdue, and she had signed Purdue's 2007

settlement agreement. In 2013, she admitted that Purdue had the list, and said Purdue would not agree to disclose it to authorities because, “I don’t really want to open up an opportunity for folks come in here and start looking and second-guessing.”

744. Abrams and Purdue’s directors knew they had reason to fear scrutiny. The state of Kentucky was prosecuting a lawsuit against Purdue for deceiving doctors and patients about opioids. Purdue’s lawyers surveyed residents who could be on the jury. One-third knew someone who overdosed or was seriously hurt taking a Purdue opioid, and 29 percent knew someone who died. Purdue itself filed those statistics in court.

745. In 2014, Edward Mahony, the Executive Vice President, CFO, and Treasurer of Purdue stated that the Kentucky lawsuit was so significant that it could “jeopardize Purdue’s long-term viability.” That same year, the Governor of Massachusetts declared the opioid crisis a public health emergency.

746. In 2016, the CDC published the *CDC Guideline for Prescribing Opioids for Chronic Pain* to try to stop dangerous opioid prescribing.

747. In 2017, the President of the United States declared the opioid crisis a national public health emergency.

748. PPI’s directors knew or should have known about these warnings and many others.

749. The directors knew about, allowed, and directed Purdue’s deception. They oversaw Purdue’s scheme to send sales representatives to visit doctors thousands of times. They oversaw Purdue’s scheme to hire top prescribers to promote its opioids. They oversaw Purdue’s effort to get more patients on higher doses of opioids for longer periods. They were aware of, allowed and directed the content of the messages conveyed in Purdue’s marketing.

750. The directors of PPI controlled PPLP. The quarterly reports distributed to the directors of PPI demonstrate that the directors in fact controlled both PPI and PPLP. The reports and minutes make clear that the directors of PPI were kept fully informed of the activities of Purdue in the areas "Finance," "Sales & Marketing," "Manufacturing & Supply Chain," "Quality," "Research & Development," "Discovery Research," "Licensing & Business Development," "Corporate Compliance," "External Affairs," "Health Policy," "Human Resources," and "Information Technology" — all of which were overseen by the directors.

751. The directors oversaw Purdue's sales representatives. Richard Sackler testified that the sales representatives were the main way that Purdue promoted its opioids. He testified that the key to getting doctors to prescribe and keep prescribing Purdue opioids was regular visits from the sales force. The Board tracked the exact number of sales representatives and the exact number of visits they made to urge doctors to prescribe Purdue opioids. The Board knew which drugs were promoted; how many visits sales representatives averaged per workday; how much each visit cost Purdue; and the company's plan for sales visits in each upcoming quarter. The Board approved specific plans to hire new sales representatives, hire and promote new District and Regional managers, and create sales "territories" in which representatives would target doctors.

752. The directors oversaw the tactics that sales representatives used to push opioids. A Board report analyzed a Purdue initiative to use iPads during sales visits, which increased the average length of the sales meeting with the doctor to "16.7 minutes in front of the customer."

753. The directors oversaw promotional claims that representatives presented to doctors during sales visits. They received reports, for example, that a "review of call notes" recorded by Purdue sales representatives "suggested potential comparative claims of superiority of Purdue

products relative to competitors," and deceptive promotion of opioids as treatment for "minor pain," including hundreds of examples of deceptive marketing that required "extensive remedial actions."

754. The directors oversaw Purdue's research, including research that contradicted its marketing. The Board received reports about studies of Purdue opioids in "opioid-naïve" patients and patients with osteoarthritis, down to the details of the strategy behind the studies and the enrollment of the first patients.

755. The directors oversaw Purdue's improper response to signs of "abuse and diversion" by high-prescribing doctors. The Board was told exactly how many "Reports Of Concern" Purdue sales representatives submitted to the company about doctors they visited to promote opioids (572 Reports Of Concern in the July 2007 Board report); and how many "field inquiries" Purdue had decided to conduct in response to the reports (21 inquiries in response to 572 Reports Of Concern).

756. The directors even monitored sales representatives' emails. Purdue held thousands of face-to-face sales meetings with doctors, but the company prohibited its sales representatives from writing emails to doctors, which could create evidence of Purdue's misconduct. When Purdue found that some sales representatives had emailed doctors, the company conducted an "investigation" and reported to the Board that sales representatives had been disciplined and that their emails would be discussed at the Board meeting.

757. The directors also oversaw Purdue's strategy to pay high prescribers to promote Purdue opioids. A report for the Board listed the exact number of conferences and dinner meetings, with attendance figures, and assured the directors: "We are tracking the prescribing trends of these attendees following the programs and will report the results in future reports." The Board was told

the amounts paid to certain doctors, and they received detailed reports on the Return on Investment that Purdue gained from paying doctors to promote its drugs. The Board was told that Purdue would allow a "spending limit for gifts" of $750 per doctor per year; and that the directors should personally report when they gave money, meals, or gifts to doctors to promote Purdue drugs. The Board was told explicitly that paying doctors to promote opioids was "a high risk activity, in view of the potential for off-label or other improper promotional conduct by third parties during such activities." When Congress required disclosure of drug company payments to doctors, the Board was told there were "significant compliance implications" for Purdue.

758. The directors also oversaw Purdue's strategy to push patients to higher doses of opioids — which are more dangerous, more addictive, and more profitable. The Board routinely received reports on Purdue's efforts to push patients to higher doses. A report alerted the Board that "Net sales of the 40 and 80 mg strengths of OxyContin" had fallen below Purdue's targets in the fall of 2010 and were $85 million below budget. By summer, the Board learned that income was $500 million below budget "mainly due to declining sales in 40 mg and 80 mg strengths. By fall, the Board reviewed an assessment that Purdue had lost more than $800 million in revenue because patients weren't taking enough 40 mg and 80 mg doses. The Board dug into the issue. Multiple reports to the Board identified as a "threat" an initiative by public health authorities to save lives by requiring doctors to consult with pain specialists before prescribing opioid doses higher than 80mg/day. The CEO and directors oversaw Purdue's effort to push back against that public health initiative. Executives were pleased to report to the directors in 2013 that "initiatives to validate increased total daily doses are having impact in the field."

759. The directors also oversaw Purdue's scheme to use higher doses of opioids to keep patients on drugs for longer periods of time. The Board received detailed reports of how many

patients stayed on Purdue's opioids for long periods (for example, longer than 35 days), along with Purdue's internal research showing that getting patients on higher doses keeps them on the drugs longer — all of which puts patients at greater risk of addiction and death. The Board received the confidential results of a study of 57,000 patients that Purdue performed explicitly to determine how opioid dose "influences patient length of therapy." The results showed that patients on the highest doses "are the most persistent." The "Recommended Actions" presented to the Board included "additional workshops for the sales force" and "specific direction" to the sales representatives about using higher doses to keep patients on drugs longer.

760. The Board was told in writing that encouraging higher doses "is a focal point of our promotion," and that sales representatives would "emphasize the importance" of increasing patients' opioid doses, as soon as 3 days after starting treatment. The Board even tracked specific sales materials, such as "two new patient profiles designed to improve patient identification and titration" – to get more opioid-naïve and elderly patients on higher doses of opioids for longer periods of time. The Board was told the exact research behind the sales strategy: higher doses would keep patients on drugs longer because Purdue had found that "83% of patients who discontinued were never titrated to higher doses." The directors knew or should have known that Purdue's sales strategy was deceptive and that putting patients on opioids at higher doses and for longer periods increased the risk of addiction, overdose, and death.

761. The directors also oversaw Purdue's strategy of using "savings cards" to get patients on Purdue opioids for longer periods. The Board knew how many thousands of cards were used each quarter, how the company calculated the Return On Investment, and that the explicit goal of the program was to hook patients to "remain on therapy longer."

762. The directors also oversaw Purdue's strategy to target prescribers who did not have special training in opioids (primary care doctors, nurse practitioners, and physician assistants) because they "show the highest responsiveness" to Purdue's sales push. Purdue continued that strategy even though the DEA had expressed concern that Purdue was promoting opioids to clinicians who were not adequately trained in pain management. The directors also oversaw Purdue's strategy to target elderly patients by promotion "targeted to HCPs that practice in the long term care setting," even down to the details of advertising that "leverages images of older patients." The directors knew or should have known that Purdue's sales strategy was deceptive and that targeting primary care doctors and elderly patients increased the risk of addiction, overdose, and death.

763. The directors also oversaw Purdue's push to steer patients away from safer alternatives. They tracked the company's effort to emphasize "the true risk and cost consequence of acetaminophen-related liver toxicity." The Board even oversaw Purdue's deceptive websites, and received reports about the specific section that was found to be deceptive by the New York Attorney General.

764. The directors also oversaw Purdue's response to signs that patients were being harmed. Reports of harm came in by the hundreds and even thousands. One Board report explained that "in excess of 5,000 cases with alleged adverse events have already been received and processed by Drug Safety and the Litigation Support group" during a single quarter.

765. Each of the reports described above was sent to every Sackler Defendant on the Board at the time they were prepared.

766. Stuart Baker also received all of the reports described above.

## VII. THE OPIOIDS THE DEFENDANTS SOLD MIGRATED INTO OTHER JURISDICTIONS

767. As the demand for prescription opioids grew, fueled by their potency and purity, interstate commerce flourished: opioids moved from areas of high supply to areas of high demand, traveling across state lines in a variety of ways.

768. The Defendants' failure to control the supply chain and prevent diversion adversely affected communities throughout the United States, including in Plaintiff's Community. Once diverted, opioids do not stay put. Rather, diverted opioids move from areas of high supply to areas of high demand, traveling across state lines in a variety of ways.

769. First, prescriptions written in one state may, under some circumstances, be filled in a different state. More significantly, however, individuals transported opioids from one jurisdiction specifically to sell them.

770. When authorities in states such as Ohio and Kentucky cracked down on opioid suppliers, out-of-state suppliers filled the gaps. Florida in particular assumed a prominent role, as its lack of regulatory oversight created a fertile ground for pill mills. Residents of New York and other states would simply drive to Florida, stock up on pills from a pill mill, and transport them back home to sell. The practice became so common that authorities dubbed these individuals "prescription tourists."

771. In particular, the I-95 corridor was one route by which diverted prescription opioids travelled from Florida northward to other states, including, in particular Plaintiff's Community.

## VIII. PLAINTIFF-SPECIFIC FACTS

772. The distribution and diversion of opioids among Plaintiff's members and beneficiaries created the foreseeable opioid crisis and opioid public nuisance for which Plaintiff seeks relief.

773. The International Union of Painters Allied Trades 1974 provides health and other benefits to eligible members.

774. As a result of the Defendants' actions detailed above, Plaintiff has spent significant amounts of money each year for purchases of prescription opioids (and related medical services) for its members and their families.

775. Plaintiff self-funds its own pharmacy benefits plan, through which it pays prescription drug costs for covered employees. Through this plan, Plaintiff pays for opioids prescribed by physicians to covered members and their family members.

776. Plaintiff pays significant sums for the costs of visits to doctors' offices when covered members and their family members visit doctors to obtain opioid prescriptions. Many such individuals visit their doctors on a recurring basis due to Defendants' coordinated efforts to create a market for long term opioid treatments.

777. Plaintiff pays significant costs for opioid addiction treatment for covered members and beneficiaries. These costs include, *e.g.*, addiction counseling, rehabilitation costs (inpatient and outpatient), overdose costs (ambulance and emergency room visits), and costs to treat infants born with NAS.

778. Plaintiff also pays for medical care needed to treat opioid side effects such as opioid-induced constipation, and other health effects such as hepatitis C virus (HCV) and heart valve infections.

779. National data establish that medical costs incurred by insurers increase by an average of approximately $15,000 per annum for individuals who suffer from opioid abuse or

addiction.[4] Plaintiff therefore incurs no less than this amount for medical costs per year for each affected member or beneficiary abusing or addicted to opioids.

780. Many of Plaintiff's members have been prescribed opioids in connection with injuries sustained at work. Those employees often remain out of work for extended periods of time due to prolonged opioid dependence. The National Council on Compensation Insurance has noted there is "ample evidence that long-term opioid use leads to longer [worker's compensation] claim duration, long-term disability, higher costs, and higher medical expenses."[5] In light of the addictive nature of opioids, Plaintiff has incurred costs for workers' compensation claims for longer periods than it otherwise would absent Defendants' conduct in creating the opioid epidemic.

781. Plaintiff members are particularly susceptible to the coordinated efforts of the Defendants because they work in a physically demanding field on a daily basis. Their work exposes them to the types of injuries and pains that the Defendants knowingly and intentionally, through the actions detailed above, targeted for treatment by their unsafe products.

782. Plaintiff members have experienced lost productivity as a result of members' work absences due to opioid abuse and addiction, and lost productivity in workers who do show up for work but are impaired by opioid use or withdrawal.

783. Opioid addiction and overdose have reached epidemic levels over the past decade. On March 22, 2016, the FDA recognized opioid abuse as a "public health crisis" that has a "profound impact on individuals, families and communities across our country."

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[4] Noam Kirson *et al*., *The Economic Burden of Opioid Abuse: Updated Findings*, Journal of Managed Care & Specialty Pharmacy, at 437 (April 2017) ("Opioid abusers generate an average of $14,810 in excess costs to payers in the 6 months before and after the initial abuse episode."), *available at* http://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.16265.

[5] NCCI *Issues Report: Worker's Compensation 2012*, at pg. 24, *available at* http://www.akleg.gov/basis/get_documents.asp?session=29&docid=2112.

784. Governor Cuomo launched a statewide taskforce to combat Opioids and heroin. The rising numbers of persons addicted to opioids have led to significantly increased health care costs as well as a dramatic increase of social problems, including drug abuse and diversion and the commission of criminal acts to obtain opioids throughout the United States, including among the Plaintiff's Community and membership. Consequently, public health, safety, and welfare throughout the United States, including the Plaintiff's Community and membership, has been significantly and negatively impacted due to the Defendants' acts and omissions.

785. A 2016 Centers for Disease Control and Prevention study estimated the national economic impact of prescription opioid overdoses, abuse and dependence to be $78.5 billion dollars annually. The study broke down the distribution of this impact further:

a. Lost Productivity: $42 billion (53.3%)

b. Health Insurance: $26.1 billion (33.3%)

c. Criminal Justice: $7.6 billion (9.7%)

d. Substance Abuse Treatment: $2.8 billion (3.6%)

786. The economic impact of prescription opioid overdoses on Plaintiff is well in line with national trends. As a direct, foreseeable, and proximate consequence of the Defendants' egregious conduct, Plaintiff paid, and continues to pay, millions of dollars for health care costs that stem from prescription opioid dependency created by the Defendants' wrongful acts and omissions. These costs include unnecessary and excessive opioid prescriptions; substance abuse treatment services; emergency response services; hospital services and other medical costs; lost productivity costs; education and prevention program costs; costs for children and youth services; and other human services; among others. Additionally, these increased costs place a burden on the funding available for current members, which will have longstanding negative impacts on the

funding available in the future for current and future members. Moreover, these avoidable and unnecessary financial burdens placed on Plaintiff's fund as a result of the Defendants' actions will limit the fund's ability to mature and grow, which will undoubtedly have an impact on the amount and type of health services that the fund will be able to provide to all members in the future, not just those directly linked to the current opioid crisis.

787. New York is experiencing an unprecedented epidemic of drug related overdose death. In 2017, there were 3224 overdose deaths in New York involving opioids, a rate of 16.1 deaths per 100,000 persons, higher than the national average rate of 14.6 deaths per 100,000.

788. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which the Plaintiff seeks relief. These damages have been suffered, and continue to be suffered, directly by the Plaintiff.

789. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

790. Plaintiff has standing to bring an action for the opioid epidemic nuisance created by Defendants.

## IX. THE DEFENDANTS CONSPIRED TO ENGAGE IN THE WRONGFUL CONDUCT COMPLAINED OF HEREIN AND INTENDED TO BENEFIT BOTH INDEPENDENTLY AND JOINTLY FROM THEIR CONSPIRACY

### A. Conspiracy Among Manufacturer Defendants

791. The Manufacturer Defendants agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers, and health care payors through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids, to increase sales, revenue, and profit from their opioid products.

792. This interconnected and interrelated network relied on the Manufacturing Defendants' collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by the Manufacturing Defendants intended to mislead consumers and medical providers of the appropriate uses, risks, and safety of opioids.

793. The Manufacturing Defendants' collective marketing scheme to increase opioid prescriptions, sales, revenues and profits centered around the development, the dissemination, and reinforcement of nine false propositions: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition dubbed "pseudo addiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

794. The Manufacturing Defendants knew that none of these propositions is true and that there was no evidence to support them.

795. Each Manufacturing Defendant worked individually and collectively to develop and actively promulgate these nine false propositions in order to mislead physicians, patients, health care providers, and healthcare payors regarding the appropriate uses, risks, and safety of opioids.

796. What is particularly remarkable about the Manufacturing Defendants' effort is the seamless method in which the Manufacturing Defendants joined forces to achieve their collective goal: to persuade consumers and medical providers of the safety of opioids, and to hide their actual

risks and dangers. In doing so, the Manufacturing Defendants effectively built a new – and extremely lucrative – opioid marketplace for their select group of industry players.

797. The Manufacturing Defendants' unbranded promotion and marketing network was a wildly successful marketing tool that achieved marketing goals that would have been impossible to have been met by a single or even a handful of the network's distinct corporate members.

798. For example, the network members pooled their vast marketing funds and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front Groups. These collaborative networking tactics allowed each Manufacturing Defendant to diversify its marketing efforts, all the while sharing any risk and exposure, financial and/or legal, with other Manufacturing Defendants.

799. The most unnerving tactic utilized by the Manufacturing Defendants' network, was their unabashed mimicry of the scientific method of citing "references" in their materials. In the scientific community, cited materials and references are rigorously vetted by objective unbiased and disinterested experts in the field, scientific method, and an unfounded theory or proposition would, or should, never gain traction.

800. Manufacturing Defendants put their own twist on the scientific method: they worked together to manufacture wide support for their unfounded theories and propositions involving opioids. Due to their sheer numbers and resources, the Manufacturing Defendants were able to create a false consensus through their materials and references.

801. An illustrative example of the Manufacturing Defendants' utilization of this tactic is the wide promulgation of the Porter & Jick Letter, which declared the incidence of addiction "rare" for patients treated with opioids. The authors had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These

patients were ***not*** given long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctor supervision.

802. Nonetheless, Manufacturing Defendants widely and repeatedly cited this letter as proof of the low addiction risk in connection with taking opioids despite its obvious shortcomings. Manufacturing Defendants' egregious misrepresentations based on this letter included claims that less than one percent of opioid users became addicted.

803. Manufacturing Defendants' collective misuse of the Porter & Jick Letter helped the opioid manufacturers convince patients and healthcare providers that opioids were not a concern. The enormous impact of Manufacturing Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June, 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented." In particular, the authors of this letter explained:

> [W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crises by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy…

804. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, the Manufacturer Defendants committed overt acts in furtherance of their conspiracy.

**B. Conspiracy Among Manufacturer Defendants and Distributor Defendants**

805. In addition, and on an even broader level, Manufacturer Defendants and Distributor Defendants took advantage of the industry structure, including end-running its internal checks and balances, to their collective advantage. Manufacturer Defendants and Distributor Defendants agreed among themselves to increasing the supply of opioids and fraudulently increasing the

quotas that governed the manufacture and supply of prescription opioids. These Defendants did so to increase sales, revenue, and profit from their opioid products.

806. The interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between Defendants in a tightly knit industry. The Manufacturing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

807. Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, as set forth more fully below and in Count 11RICO, below, including, for example, membership in the Healthcare Distribution Alliance.

808. Manufacturer Defendants and Distributor Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA to report suspicious orders. These Defendants overwhelmingly agreed on the same approach – to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. These Defendants' agreement to restrict reporting provided an added layer of insulation from the DEA scrutiny for the entire industry as these Defendants were thus collectively responsible for each other's compliance with their reporting obligations. These Defendants were aware, both individually and collectively, of the suspicious orders that flowed directly from Defendants' facilities.

809. Manufacturer Defendants and Distributor Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, they had an incentive to communicate with

each other about the reporting or suspicious orders to ensure consistency in their dealings with the DEA.

810. Manufacturer Defendants and Distributor Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

811. The desired consistency, and collective end goal was achieved. Manufacturer Defendants and Distributor Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

## X. STATUTES OF LIMITATIONS ARE TOLLED AND DEFENDANTS ARE ESTOPPED FROM ASSERTING STATUTES OF LIMITATIONS AS DEFENSES

### A. Continuing Conduct.

812. Plaintiff contends it continues to suffer harm from the unlawful actions by the Defendants.

813. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants have not ceased. The public nuisance remains unabated. The conduct causing the damages continues.

### B. Equitable Estoppel and Fraudulent Concealment

814. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiff and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff, and Plaintiff's Community, that they were undertaking efforts to comply with their obligations under

the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. The Defendants affirmatively assured the public, including the Plaintiff, that they are working to curb the opioid epidemic.

815. The Defendants were deliberate in taking steps to conceal their conspiratorial behavior and played an active role in the deceptive marketing and the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

816. The Manufacturing Defendants deliberately worked through Front Groups purporting to be patient advocacy and professional organizations, through public relations companies hired to work with the Front Groups and through paid KOLs to secretly control messaging, influence prescribing practices and drive sales. The Manufacturing Defendants concealed their role in shaping, editing, and approving the content of prescribing guidelines, informational brochures, KOL presentations and other false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers and the public at large. They concealed the addictive nature and dangers associated with opioid use and denied blame for the epidemic attributing it instead solely to abuse and inappropriate prescribing. They manipulated scientific literature and promotional materials to make it appear that misleading statements about the risks, safety and superiority of opioids were actually accurate, truthful, and supported by substantial scientific evidence. Through their public statements, omissions, marketing, and advertising, the Manufacturing Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

817. Defendants also concealed from Plaintiff the existence of Plaintiff's claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the

public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including Plaintiff, and deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

818. Plaintiff did not discover the nature, scope and magnitude of Defendants' misconduct, and its full impact on New Yorknd could not have acquired such knowledge earlier through the exercise of reasonable diligence.

819. The Manufacturing Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Plaintiff's Community deceived the medical community, consumers, the State, and Plaintiff's Community.

820. Further, Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities.

821. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff. Plaintiff did not know and did not have the means to know the truth, due to Defendants' actions and omissions.

822. The Plaintiff reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

## XI. FACTS PERTAINING TO PUNITIVE DAMAGES

823. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs. The Manufacturer Defendants knew there was no support for their claims that

addiction was rare, that addiction risk could be effectively managed, that signs of addiction were merely "pseudo addiction," that withdrawal is easily managed, that higher doses pose no significant additional risks, that long-term use of opioids improves function, or that time-release or abuse-deterrent formulations would prevent addiction or abuse. Nonetheless, they knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

824. All of the Defendants, moreover, knew that large and suspicious quantities of opioids were being poured into communities throughout the United States, yet, despite this knowledge, took no steps to report suspicious orders, control the supply of opioids, or otherwise prevent diversion. Indeed as described above, Defendants acted in concert together to maintain high levels of quotas for their products and to ensure that suspicious orders would not be reported to regulators.

825. Defendants' conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. This ongoing course of conduct knowingly, deliberately, and repeatedly threatened and accomplished harm and risk of harm to public health and safety, and large-scale economic loss to communities and government liabilities across the country.

826. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. The Manufacturer Defendants' fraudulent wrongdoing was done with a particularly gross and conscious disregard.

**A. The Manufacturer Defendants Persisted in Their Fraudulent Scheme Despite Repeated Admonitions, Warnings, and Even Prosecutions**

827. So determined were the Manufacturer Defendants to sell more opioids that they simply ignored multiple admonitions, warnings and prosecutions. These governmental and regulatory actions included:

***1. FDA Warnings to Janssen Failed to Deter Janssen's Misleading Promotion of Duragesic***

828. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of "homemade" promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance." The March 30, 2000 letter detailed numerous ways in which Janssen's marketing was misleading.

829. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products." The September 2, 2004 letter detailed a series of unsubstantiated, false, or misleading claims.

830. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been "'examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch'" and noted the possibility "that patients and physicians might be

unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

### *2. Governmental Action, Including Large Monetary Fines, Failed to Stop Cephalon from Falsely Marketing Actiq for Off-Label Uses*

831. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CMEs to promote off-label uses.

832. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Cephalon has continued its deceptive marketing strategy.

### *3. FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora*

833. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: "Fentora should not be used to treat any type of short-term pain." Indeed, the FDA specifically denied Cephalon's application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

834. Flagrantly disregarding the FDA's refusal to broaden the indication for Fentora, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to

broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

835. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in Pharmacy Times titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."

#### ***4. A Guilty Plea and a Large Fine Did Not Deter Purdue from Continuing Its Fraudulent Marketing of OxyContin***

836. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay $7.5 million in fines.

837. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund

seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. At least until early 2018, Purdue continued to deceptively market the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly $900 million dollars on lobbying and political contributions—eight times what the gun lobby spent during that period.

### B. Repeated Admonishments and Fines Did Not Stop Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion

838. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

839. In a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die." He further explained that:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.

840. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."

841. Government actions against the Defendants with respect to their obligations to control the supply chain and prevent diversion include:

a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida Distribution Center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the

DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

g. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and

h. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.

842. McKesson's deliberate disregard of its obligations was especially flagrant. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 McKesson MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program."

843. Despite its 2008 agreement with DEA, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program it agreed to. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers and bypassed suspicious order reporting procedures set forth in the CSMP. It failed to take these actions despite its awareness of the great probability that its failure to do so would cause substantial harm.

844. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as a failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA. McKesson's 2017 agreement with DEA documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."

845. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty than the $150 million ultimately agreed to for McKesson's continued and renewed breach of its duties, as much as a billion dollars, and delicensing of certain facilities. A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."

846. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant Special Agent Schiller, who described McKesson as a company that killed people for its own financial gain and blatantly ignored the CSA requirement to report suspicious orders:

> DAVID SCHILLER: If they would stayed in compliance with their authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.
>
> * * *

They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.

[INTERVIEWER:] And they had none.

DAVID SCHILLER: They weren't reporting any. I mean, you have to understand that, nothing was suspicious?

847. Following the 2017 settlement, McKesson shareholders made a books and records request of the company. According to a separate action pending on their behalf, the Company's records show that the Company's Audit Committee failed to monitor McKesson's information reporting system to assess the state of the Company's compliance with the CSA and McKesson's 2008 Settlements. More particularly, the shareholder action alleges that the records show that in October 2008, the Audit Committee had an initial discussion of the 2008 Settlements and results of internal auditing, which revealed glaring omissions; specifically:

a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review";

b. "[d]ocumentation evidencing new customer due diligence was incomplete";

c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete"; and

d. Internal Audit "identified opportunities to enhance the Standard Operating Procedures."

848. Yet, instead of correcting these deficiencies, at that time, for a period of more than four years, the Audit Committee failed to address the CSMP or perform any more audits of McKesson's compliance with the CSA or the 2008 Settlements, the shareholder action's description of McKesson's internal documents reveals. During that period of time, McKesson's Audit Committee failed to inquire whether the Company was in compliance with obligations set

forth in those agreements and with the controlled substances regulations more generally. It was only in January 2013 that the Audit Committee received an Internal Audit report touching on these issues.

849. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted. Quite the opposite, "their bad acts continued and escalated to a level of egregiousness not seen before." According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in the *Washington Post*, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings." "Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."

850. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Purdue claims that health care providers added to the database no longer were detailed, and that sales representatives received no compensation tied to these providers' prescriptions.

851. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Purdue's former senior compliance officer acknowledged in an interview with the *Los Angeles Times* that in five years of investigating

suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

852. Purdue was equally irresponsible with respect to suspicious prescribers. For example, as discussed above, despite Purdue's knowledge of illicit prescribing from one Los Angeles clinic which its district manager called an "organized drug ring" in 2009, Purdue did not report its suspicions until long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

853. The New York Attorney General found that Purdue placed 103 New York health care providers on its "No-Call" List between January 1, 2008 and March 7, 2015, and yet Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period.

854. The New York Attorney General similarly found that Endo knew, as early as 2011, that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

855. As all of the governmental actions against the Manufacturing Defendants and against all the Defendants shows, Defendants knew that their actions were unlawful, and yet deliberately refused to change their practices because compliance with their legal obligations would have decreased their sales and their profits.

## CLAIMS FOR RELIEF

## FIRST CAUSE OF ACTION

## PUBLIC NUISANCE

## (AGAINST ALL DEFENDANTS)

856. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

857. Defendants engaged in conduct that caused a public nuisance.

858. Defendants, individually and acting through their employees and agents, and in concert with each other, have knowingly, intentionally, recklessly, or negligently engaged in conduct or omissions which unreasonably interferes with the public health, safety, peace, comfort, convenience, or quality of life.

859. The significant adverse impact of the Defendants' conduct on Plaintiff's members and beneficiaries has caused and continues to cause tremendous harm to Plaintiff, including increased health care costs related to treatment of pain and addiction, as well as the diminishment of funds used to pay for current and future healthcare costs of its members.

860. Defendants' conduct is not insubstantial or fleeting. Indeed, Defendants' unlawful conduct has so severely impacted public health on every geographic and demographic level that the public nuisance perpetrated by Defendants' conduct is commonly referred to as a "crisis" or an "epidemic." It has caused deaths, serious injuries, and a severe disruption of public health, safety, peace, comfort, convenience, and quality of life; it is ongoing, and it is producing permanent and long-lasting damage.

861. By reason of the foregoing, Plaintiff has been injured and continues to be injured in that it has paid and continues to pay for long-term opioid treatment using opioids manufactured or distributed by Defendants or by other drug makers. Plaintiff has suffered additional damages

and continues to suffer damage for the additional costs of providing and using opioids long-term to treat chronic pain.

862. As a direct and foreseeable consequence of Defendants' conduct, Plaintiff has paid, and continues to pay, millions of dollars for health care costs that stem from prescription opioid dependency created by Defendants' conduct. These costs include unnecessary and excessive opioid prescriptions, substance abuse treatment services, ambulatory services, emergency department services, and inpatient hospital services, among others. Defendants' conduct has also caused the diminishment of the funds available to pay for other types of healthcare treatment for members and their families.

863. By reason of the foregoing, the Defendants are liable, jointly and severally, to the Plaintiff for damages of millions of dollars resulting from this public nuisance in an amount to be determined at trial, as well as punitive damages in an amount to be determined at trial, plus costs and attorneys' fees.

WHEREFORE, Plaintiff respectfully requests that this Court enter an order (a) awarding judgment in its favor and against the Defendants on this Cause of Action; (b) requiring the Defendants to abate the public nuisance to the fullest extent allowed by law, including the creation of an abatement fund; (c) compelling the Defendants to pay the cost of the suit, including attorneys' fees; (d) awarding Plaintiff prejudgment interest and delay damages; and (e) awarding Plaintiff such other, further, and different relief as this Honorable Court may deem just.

## SECOND CAUSE OF ACTION

## NEGLIGENCE

## (AGAINST ALL DEFENDANTS)

864. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

865. Defendants owed Plaintiff a duty, including a preexisting duty, to not expose Plaintiff to an unreasonable risk of harm.

866. Defendants had a legal duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in manufacturing, advertising, marketing, selling and/or distributing opioids.

867. Defendants had a duty not to breach the standard of care established under numerous laws and regulations to report suspicious prescribing and to maintain systems to detect and report such activity.

868. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Defendants' conduct in marketing, distributing, and selling dangerously addictive drugs requires a high degree of care and places them in a position of great trust and responsibility vis a vis Plaintiff. Their duty cannot be delegated.

869. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

870. Defendants breached their duty to Plaintiff by, inter alia:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

871. The Manufacturer Defendants breached their duty to Plaintiff by deceptively marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

872. Plaintiff does not allege that Defendants were negligent for failure to protect from harm. Rather, Defendants engaged in conduct the foreseeable result of which was to cause harm to Plaintiff.

873. Defendants have engaged in affirmative acts of creating an illegal, secondary prescription opioid market by failing to exercise adequate control over the marketing, distribution, and sale of their prescription opioids.

874. Defendants were negligent by marketing, distributing, and selling opioids in a way that created and fostered an illegal, secondary prescription opioid market that resulted in a foreseeable and unreasonable risk of harm to Plaintiff.

875. The method by which Defendants created this market was by marketing, distributing, and selling opioids without regard to the likelihood that the opioids would be placed in the hands of criminals, addicts, juveniles, and others not permitted to use or possess prescription opioids.

876. A reasonably prudent opioid manufacturer and distributor should have anticipated an injury to Plaintiff and its members as a probable result of marketing, distributing, and selling prescription opioids in this manner.

877. It was reasonably foreseeable that Defendants' actions and omissions would result in the harm to Plaintiff as described herein.

878. Defendants had control over their conduct in Plaintiff's community, including among Plaintiff's membership and beneficiaries. Manufacturer Defendants controlled their deceptive advertising and efforts to mislead the public, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems they developed to prevent diversion, including the criteria and process they used to identify suspicious orders, whether and to what extent they trained their employees to report and halt suspicious orders, and whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

879. Because of the Manufacturer Defendants' deceptive marketing of opioids and each of the Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

880. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious orders. Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent drug diversion.

881. Defendants are in the business of manufacturing, marketing, selling and/or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under several laws as substances posing a high potential for abuse and addiction.

882. Indeed, opioids are akin to medical grade heroin. Defendants' wrongful conduct of deceptively marketing and pushing as many opioids into the market as possible led directly to the public nuisance and harm to Plaintiff and its members – exactly as would be expected when medical grade heroin in the form of prescription opioids are deceptively marketed, flood the community, and are diverted into an illegal, secondary market.

883. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon the governmental entities associated with those communities. Indeed, it is a violation of state and federal law for Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution, whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

884. Manufacturer Defendants knew or should have known that their affirmative misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing narcotic drugs created an unreasonable risk of harm. The Defendants' sales data, reports from sales representatives, and internal documents, should have put them on notice that such harm was not only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively

withhold information about the dangers of opioids from Plaintiff, physicians, patients, and the public.

885. Defendants conduct was negligence *per se* in that Defendants violated several laws and regulations. Plaintiff and its members were parties intended to be protected by such laws and whose injuries said laws were designed to prevent. Defendants' violations of these laws proximately caused injury to Plaintiff.

886. Defendants also violated New York statutes and regulations, including the controlled substances laws, by, inter alia:

a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

887. As a direct and proximate result of Defendants' negligence and/or negligence *per se*, Plaintiff has suffered and will continue to suffer economic damages including, but not limited to, increased healthcare costs for its members and beneficiaries, as well as the diminishment of funds available to pay for their other health care needs.

888. As a direct and proximate result of Defendants' negligence and/or negligence *per se*, Plaintiff has suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

889. As a direct and proximate result of Defendants' negligent, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, there is now a national opioid epidemic that has caused enormous harm and injury to the public, including Plaintiff's members and beneficiaries.

890. Defendants' misconduct alleged in this case is ongoing and persistent.

891. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a party would reasonably expect to occur and is not part of the normal and expected costs of existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort that can reasonably be expected.

892. Plaintiff has incurred expenditures for special programs over and above Plaintiff's ordinary services.

893. Plaintiff has suffered an indivisible injury as a result of the tortious conduct of Defendants.

894. The tortious conduct of each Defendant was a substantial factor in producing harm to Plaintiff.

895. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

WHEREFORE, Plaintiff respectfully requests that this Court enter an order (a) awarding judgment in its favor and against the Defendants on Plaintiff's Cause of Action; (b) compelling the Defendants to pay Plaintiff's direct and consequential damages; (c) awarding Plaintiff prejudgment interest and delay

damages; (d) compelling the Defendants to pay the cost of the suit, including attorneys' fees; and (e) awarding Plaintiff such other, further, and different relief as this Honorable Court may deem just.

## THIRD CAUSE OF ACTION

## UNJUST ENRICHMENT

## (AGAINST ALL DEFENDANTS)

896. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

897. Defendants have knowingly and unjustly retained a benefit to Plaintiff's detriment, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

898. By illegally and deceptively promoting opioids to treat chronic pain, directly, through their control of third parties, and by acting in concert with third parties, Defendants have unjustly enriched themselves at Plaintiff's expense. Plaintiff has made payments for opioid prescriptions, and Defendants benefited from those payments. Because of their deceptive promotion of opioids, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and the Plaintiff lacks a remedy provided by law.

899. In addition, and by reason of the foregoing, the Plaintiff was injured and continues to be injured in that Defendants' ongoing concerted actions in illegally and deceptively marketing opioids caused doctors and other health care providers to prescribe and the Plaintiff to pay for long-term opioid treatment using opioids manufactured by Defendants or by other drug makers, Defendants caused and are responsible for those costs and claims. The Plaintiff has suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

900. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within Plaintiff's Community and among its members and beneficiaries, including from opioids foreseeably and deliberately diverted within and among Plaintiff's Community, membership, and beneficiaries.

901. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

902. Plaintiff has expended substantial amounts of money in an effort to remedy or mitigate the harms to its members and beneficiaries caused by Defendants' conduct.

903. These expenditures include the provision of healthcare services and treatment services to members and their families who use opioids, as well as the diminishment of funds available for other needs.

904. These expenditures have helped sustain Defendants' businesses.

905. Plaintiff has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.

906. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

907. Plaintiff has paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their deceptive marketing of prescription opioids, Defendants obtained enrichment they would not otherwise have obtained. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained

enrichment they would not otherwise have obtained. The enrichment was without justification and Plaintiff lacks a remedy provided by law.

908. Defendants' misconduct alleged in this case is ongoing and persistent.

909. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort that Plaintiff would reasonably expect to occur and is not part of the normal and expected costs of Plaintiff's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort that can reasonably be expected.

910. Plaintiff has incurred expenditures for special programs over and above Plaintiff's ordinary services.

911. The Purdue-Related Additional Defendants are liable not only for the unjust enrichment of Purdue, but also for their own unjust enrichment, including, but not limited to, all of the distributions they have received, directly or indirectly, from Purdue or from any of Purdue-related entities from the sale of opioids.

WHEREFORE, Plaintiff respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on this Cause of Action; (b) compelling the Defendants to pay Plaintiff's direct and consequential damages; (c) compelling Defendants to disgorge all unjust enrichment to Plaintiff; (d) awarding Plaintiff prejudgment interest and delay damages; (e) compelling the Defendants to pay the cost of the suit, including attorneys' fees; and (f) awarding Plaintiff such other, further, and different relief as this Honorable Court may deem just.

## FOURTH CAUSE OF ACTION

## FRAUD

## (AGAINST ALL DEFENDANTS)

912. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

913. Manufacturing Defendants violated their duty not to actively deceive by intentionally and unlawfully making knowingly false statements, and by intentionally and unlawfully omitting and/or concealing information.

914. Specifically, the Manufacturing Defendants' knowing deceptions during the relevant period, which were intended to induce reliance, include but are not limited to:

a. Manufacturer Defendants' misrepresentations overstating the benefits of, and evidence for, the use of opioids for chronic pain;

b. Manufacturer Defendants' misrepresentations that the risks of long-term opioid use, especially the risk of addiction, were overblown;

c. Manufacturer Defendants' misrepresentations that opioid doses can be safely and effectively increased until pain relief is achieved;

d. Manufacturer Defendants' misrepresentations that signs of addiction were "pseudo addiction" and thus reflected undertreated pain, which should be responded to with more opioids;

e. Manufacturer Defendants' misrepresentations that screening tools effectively prevent addiction;

f. Manufacturer Defendants' misrepresentations concerning the comparative risks of NSAIDs and opioids;

g. Manufacturer Defendants' misrepresentations that opioids differ from NSAIDs in that opioids have no ceiling dose;

h. Manufacturer Defendants' misrepresentations that evidence supports the long-term use of opioids for chronic pain;

i. Manufacturer Defendants' misrepresentations that chronic opioid therapy would improve patients' function and quality of life;

j. Manufacturer Defendants' false portrayal of their efforts and/or commitment to rein in the diversion and abuse of opioids;

k. Manufacturer Defendants' misrepresentations that withdrawal is easily managed;

l. Purdue's and Endo's misrepresentations that alleged abuse-deterrent opioids reduce tampering and abuse;

m. Purdue's misrepresentations that OxyContin provides a full 12 hours of pain relief;

n. Purdue's misrepresentations that it cooperates with and supports efforts to prevent opioid abuse and diversion;

o. Mallinckrodt's misrepresentations that it meets or exceeds legal requirements for controlling against diversion of controlled substances it has been entrusted to handle;

p. Insys's misrepresentations that Subsys was appropriate for treatment of non-cancer pain and its failure to disclose that Subsys was not approved for such use;

q. Insys's misrepresentations to third-party payors to secure approval for coverage;

r. Insys's use of speaker bureaus to disguise kickbacks to prescribers;

s. Teva's misrepresentations that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use;

t. Cephalon's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of non-cancer pain;

u. Manufacturer Defendants' use of front groups to misrepresent that the deceptive statements from the sources described in this Complaint came from objective, independent sources;

v. Manufacturer Defendants' creation of a body of deceptive, misleading and unsupported medical and popular literature, advertisements, training materials, and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors; and,

w. Such other misrepresentations and deceptions outlined above.

915. By engaging in the acts and practices alleged herein, Manufacturer Defendants, in the relevant time period, with the intent that others rely on their omissions or suppression of information, omitted material facts that Manufacturer Defendants had a duty to disclose by virtue of these Defendants' other representations, including but not limited to:

a. opioids are highly addictive and may result in overdose or death;

b. no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. high dose opioids subject the user to greater risks of addiction, other injury, and/or death;

d. opioids present the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines; these omissions were made while Defendants exaggerated the risks of competing products such as NSAIDs;

e. claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

g. Purdue's and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the common route of abuse (oral abuse), can be defeated with relative ease, and may increase overall abuse;

h. Manufacturer and Distributor Defendants' failure to report suspicious prescribers and/or orders;

i. Insys's use of kickback and insurance fraud schemes;

j. Insys's failure to disclose that Subsys was not approved for non-cancer pain;

k. Cephalon's failure to disclose that Actiq and Fentora were not approved for non-cancer pain;

l. Defendants' failure to disclose their financial ties to and role in connection with KOLs, front groups, and deceptive literature and materials, as more fully described above; and

m. Such other omissions and concealments as described above.

916. In each of the circumstances described in *inter alia* the foregoing paragraph, Defendants knew that their failure to disclose rendered their prior representations untrue or misleading. Thus, Defendants had a duty not to deceive Plaintiff and its members.

917. In addition and independently, Defendants had a duty not to deceive Plaintiff because Defendants had in their possession unique material knowledge that was unknown, and not knowable, to the Plaintiff, Plaintiff's agents, Plaintiff's members and beneficiaries, physicians, and the public.

918. These Defendants made these false representations and concealed facts with knowledge of the falsity of their representations. These Defendants' false representations and concealed facts were material to the conduct and actions at issue.

919. Defendants intended and had reason to expect under the operative circumstances that the Plaintiff, Plaintiff's agents, Plaintiff's members and beneficiaries, physicians, the public, and persons on whom Plaintiff and its agents relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein and that Plaintiff would act or fail to act in reasonable reliance thereon.

920. Defendants intended that Plaintiff, Plaintiff's agents, Plaintiff's members and beneficiaries, physicians, the public, and persons on whom Plaintiff and its agents relied would rely on these Defendants' misrepresentations and omissions; Defendants intended and knew that this reasonable and rightful reliance would be induced by these Defendants' misrepresentations and omissions; and, Defendants intended and knew that such reliance would cause Plaintiff to suffer loss.

921. Plaintiff, Plaintiff's agents, Plaintiff's members and beneficiaries, the public, physicians and persons on whom Plaintiff and its agents relied, did in fact rightfully, reasonably, and justifiably rely on Defendants' representations and/or concealments, both directly and indirectly.

922. Defendants misstatements and omissions intentionally created the false narrative that their opioids were safe for the treatment of non-chronic pain and were less addictive than other treatments, which Defendants knew or should have known was false. This directly led to the misuse and diversion of their opioids and the resulting addiction epidemic. Plaintiff and its members and beneficiaries were directly and proximately injured as a result of their reliance on

Defendants misstatements and omission and Plaintiff's injuries were directly and proximately caused by this reliance because Plaintiff had to pay for the increased costs, on behalf of its members and beneficiaries, of both the improper opioid treatment and the results of the addiction epidemic.

923. As a result of these representations and/or omissions, Plaintiff proceeded under the misapprehension that the opioid crisis was simply a result of conduct by persons other than Defendants. As a consequence, these Defendants prevented Plaintiff from a more timely and effective response to the opioid crisis.

924. By reason of its reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff suffered damages.

925. Defendants' misconduct alleged in this case is ongoing and persistent.

926. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort that Plaintiff would reasonably expect to occur, and is not part of the normal and expected costs of Plaintiff's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort that can reasonably be expected.

927. Plaintiff has incurred expenditures for special programs over and above Plaintiff's ordinary services.

928. These Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

929. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. The Manufacturer Defendants' fraudulent wrongdoing was done with a particularly gross and conscious disregard.

WHEREFORE, Plaintiff respectfully requests that this Court enter an order (a) awarding judgment in its favor and against the Defendants on Plaintiff's Cause of Action; (b) compelling the Defendants to pay Plaintiff's direct and consequential damages; (c) awarding Plaintiff prejudgment interest and delay damages; (d) compelling the Defendants to pay the cost of the suit, including attorneys' fees; and (e) awarding Plaintiff such other, further, and different relief as this Honorable Court may deem just.

## FIFTH CAUSE OF ACTION

## BREACH OF IMPLIED WARRANTIES

## (AGAINST MANUFACTURING DEFENDANTS AND PURDUE RELATED DEFENDANTS)

930. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

931. Defendants, in the manufacture, marketing, sale, and distribution of opioids impliedly warranted to Plaintiff and its members and beneficiaries that these opioids were appropriate for their particular and understood ordinary purposes as presented by Defendants; namely the treatment of chronic pain and/or other long-term medical conditions.

932. Defendants and their agents, employees, servants, paid speakers, KOLs, and/or other representatives knew or should have known that Defendants' opioids were ineffective (and inherently dangerous) treatment options in the management of chronic pain and other long-term medical conditions.

933. Plaintiff reasonably relied upon the skill and judgment of Defendants and their agents, employees, servants, paid speakers, KOLs, and/or other representatives as to whether these opioids were of merchantable quality, safe, and fit for their intended uses as described by Defendants.

934. Pursuant to UCC§2-314 there exists an implied warranty of merchantability for Defendants' marketing and sale of their opioids.

935. Defendants breached this implied warranty of merchantability by promoting, marketing, selling, and distributing their opioids as being fit for the “ordinary purpose” ascribed by Defendants (i.e.- the treatment of chronic pain and/or other long-term medical conditions) when, in fact, their opioids are inappropriate, dangerous, and unfit for that purpose.

WHEREFORE, Plaintiff respectfully requests that this Court enter an order (a) awarding judgment in its favor and against the Defendants on Plaintiff's Cause of Action; (b) compelling the Defendants to pay Plaintiff's direct and consequential damages; (c) awarding Plaintiff prejudgment interest and delay damages; (d) compelling the Defendants to pay the cost of the suit, including attorneys' fees; and (e) awarding Plaintiff such other, further, and different relief as this Honorable Court may deem just.

**SIXTH CAUSE OF ACTION**

**NEGLIGENCE PER SE**

**(AGAINST ALL DEFENDANTS)**

936. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

937. Under Article 71: Food and Drugs, a drug shall be deemed misbranded as set forth in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §352) or the State Education Law (§6915) if its labeling is false or misleading in any particular. Id. at §71.05 (f)

938. The Defendants manufactured, sold, and distributed drugs that were “misbranded” under New York Law.

939. Defendants' violations of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §352) or the State Education Law (§6915) and other laws and regulations constitute negligence *per se.*

940. Defendants' acts and omissions imposed an unreasonable and foreseeable risk of harm to others separately and/or combined with the improper or unlawful acts of third parties.

941. As a proximate result of the Defendants' breach of their duties of care, Defendants and their agents have caused excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, Plaintiff has borne massive costs of these illnesses and conditions by having to provide necessary resources for these costs and claims. These damages amount to millions of dollars to Plaintiff in an amount to be determined at trial.

942. The Defendants' conduct was willful, wanton, and malicious, and was directed at the public generally, so as to justify an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter an order (a) awarding judgment in its favor and against the Defendants on Plaintiff's Cause of Action; (b) compelling the Defendants to pay Plaintiff's direct and consequential damages; (c) awarding Plaintiff prejudgment interest and delay damages; (d) compelling the Defendants to pay the cost of the suit, including attorneys' fees; and (e) awarding Plaintiff such other, further, and different relief as this Honorable Court may deem just.

## SEVENTH CAUSE OF ACTION

## NEGLIGENT MISREPRESENTATION

## (AGAINST MANUFACTURING DEFENDANTS AND PURDUE RELATED DEFENDANTS)

943. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

944. Defendants, individually and acting through their employees and agents, and in concert with one another, made misrepresentations and omissions of facts material to Plaintiff and

its members to induce them to purchase, administer, and consume opioids. These misrepresentations and/or omissions included, but were not limited to, statements that:

a. The risk of addiction from chronic opioid therapy is low

b. To the extent there is a risk of addiction, it can be easily identified and managed

c. Signs of addictive behavior are "pseudo addiction," requiring more opioids

d. Opioid withdrawal can be avoided by tapering

e. Opioid doses can be increased without limit or greater risks

f. Long-term opioid use improves functioning

g. Alternative forms of pain relief pose greater risks than opioids

h. OxyContin provides twelve hours of pain relief

i. New formulations of certain opioids successfully deter abuse

945. At all times relevant to this Complaint, Defendants, directly, through their control of third parties, and by aiding and abetting third parties, made misstatements that omitted or concealed material facts to promote the sale and use of opioids to treat chronic pain. The Defendants and their third-party allies repeatedly failed to disclose or minimized material facts about the risks of opioids, including the risk of addiction, and their risks compared to alternative treatments. Such material omissions were deceptive and misleading in their own right, and further rendered even otherwise truthful statements about opioids untrue, false, and misleading, creating a misleading impression of the risks, benefits, and superiority of opioids for treatment of chronic pain.

946. At all times relevant to this Complaint, Defendants, directly, through their control of third parties, and by aiding and abetting third parties, made and disseminated the foregoing untrue, false and misleading misstatements, and material omissions, through an array of marketing

channels, including but not limited to: in-person and other forms of detailing; speaker events, including meals, conferences, and teleconferences; CMEs; studies, and journal articles and supplements; advertisements; and brochures and other patient education materials.

947. The Defendants knew at the time of making or disseminating these misstatements and material omissions, or causing these misstatements and material omissions to be made or disseminated, that they were untrue, false, or misleading and therefore likely to deceive the public, including the Plaintiff. In addition, the Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression of the risks, benefits, and superiority of opioids.

948. In sum, the Defendants: (a) directly engaged in untrue, false, and misleading marketing; (b) disseminated the untrue, false, and misleading marketing; and (c) aided and abetted the untrue, false, and misleading marketing.

949. Defendants, in the course of their business in which they have a pecuniary interest, supplied the above false information for the guidance of others, including Plaintiff. *See* §552 of the Restatement (Second) of Torts.

950. Defendants intended that Plaintiff and its members and beneficiaries would rely on their misrepresentations and omissions and it was foreseeable that they would do so.

951. As a result of the incredible amount of resources and efforts that Defendants utilized in creating, maintaining, and disseminating these misrepresentations and omissions, Plaintiff and its members and beneficiaries reasonably relied upon these misrepresentations and omissions.

952. Given Defendants large amount of resources and knowledge, Plaintiff and its members and beneficiaries reasonably relied upon Defendants to uphold their requirements under both federal and state laws and regulations and to not commit intentional, material

misrepresentations and omissions to both federal and state law enforcement and regulatory agencies and officials.

953. As a result of its reasonable reliance upon Defendants' misrepresentation and omissions of material fact, Plaintiff has suffered actual pecuniary harm directly caused by Defendants' deceptive practices. Plaintiff was injured in that the Defendants' unbranded marketing of opioids for chronic pain caused the doctors to prescribe and the Plaintiff to pay for long-term opioid treatment using opioids manufactured or distributed by Defendants as well as other drug makers. These actions also created the diversion of these opioids and the resulting addiction epidemic, the treatment of which has caused substantial costs to Plaintiff. The Defendants caused and are responsible for those costs and claims.

954. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally, so as to justify an award of punitive damages.

WHEREFORE, Plaintiff, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against the Defendants on Plaintiff's Cause of Action; (b) compelling the Defendants to pay Plaintiff's direct and consequential damages; (c) awarding Plaintiff prejudgment interest and delay damages; (d) compelling the Defendants to pay the cost of the suit, including attorneys' fees; and (e) awarding Plaintiff such other, further, and different relief as this Honorable Court may deem just.

## EIGHTH CAUSE OF ACTION

## NEGLIGENT MARKETING

## (AGAINST ALL DEFENDANTS)

955. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

956. Defendants had a duty to protect Plaintiff and its members from unreasonable risks. Specifically, Defendants owed a duty to Plaintiff and its members and beneficiaries not to introduce into the market a drug that was unreasonably dangerous for any person to use as marketed. Furthermore, even after marketing a drug, Defendants owed a duty to Plaintiff and its members and beneficiaries to investigate reports of adverse reactions (including addiction and dependency); to monitor, report, and prevent suspicious orders that were the result of these reactions; and to warn physicians and the public promptly if such an investigation found evidence of previously unknown or undisclosed widespread and potentially serious harm, such that these risks so greatly outweigh any benefits of the drug as marketed, that the dangers are sufficient to require a drug company to pull the drug from the market, and to follow through with a rapid withdrawal of the drug from pharmacies nationwide.

957. Defendants failed in their duty to Plaintiff and its members and beneficiaries in that they unreasonably introduced their opioids into the market with the intention that they be used for the treatment of non-chronic pain, based on misstatements and omissions, which they knew or should have known would lead to widespread addiction and diversion. Their opioids, marketed in this manner, were so unreasonably dangerous and defective in design that they should have never been on the market. Before marketing these opioids in this manner, Defendants knew or should have known how dangerous and addictive they were, and they should not have marketed them in this manner. There is no warning that Defendants could have given with these opioids that would have made their marketing reasonable.

958. Furthermore, Defendants failed to investigate and report numerous adverse reaction reports, beginning as early as the 1990s; failed to meet the industry standard of care in monitoring these drugs; failed to warn physicians and the public promptly when such investigations revealed

evidence of the widespread and serious harm that these opioids were wreaking on Plaintiff's membership and beneficiaries which outweighed any benefits of these opioids; failed to withdraw these opioids from the market; and failed to monitor, report, and prevent suspicious shipments of these opioids as required by law.

WHEREFORE, Plaintiff respectfully requests that this Court enter an order (a) awarding judgment in its favor and against the Defendants on Plaintiff's Cause of Action; (b) compelling the Defendants to pay Plaintiff's direct and consequential damages; (c) awarding Plaintiff prejudgment interest and delay damages; (d) compelling the Defendants to pay the cost of the suit, including attorneys' fees; and (e) awarding Plaintiff such other, further, and different relief as this Honorable Court may deem just.

## NINTH CAUSE OF ACTION

## CIVIL CONSPIRACY (DECEPTIVE MARKETING)

## (AGAINST MANUFACTURING DEFENDANTS AND PURDUE-RELATED ADDITIONAL DEFENDANTS)

959. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

960. Manufacturing Defendants and the Purdue-Related Additional Defendants conspired with each other and with various KOLs and Front Groups to commit unlawful acts or lawful acts in an unlawful manner.

961. Defendants unlawfully marketed opioids in New York and among Plaintiff's members and beneficiaries in furtherance of that conspiracy.

962. Defendants knowingly and voluntarily agreed to engage in unfair and deceptive practices to promote the use of opioids for the treatment of chronic pain by making and disseminating false, unsubstantiated, and misleading statements and misrepresentations to

prescribers and consumers. Defendants enlisted various KOLs and Front Groups to make and disseminate these statements in furtherance of their common strategy to increase opioid sales, and the Defendants—along with the Front Groups with whom each of them conspired—knew that the statements they made and disseminated served this purpose.

963. By engaging in the conduct described in this Complaint, the Defendants agreed with Front Groups that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with one another and Front Groups, Manufacturing Defendants provided support for Front Group's deceptive statements promoting opioids and Front Groups used that support to more broadly disseminate deceptive messaging promoting opioids, which would benefit the Manufacturing Defendants' drug sales, other opioid makers' sales, and provide increased revenue to the Purdue-Related Other Defendants. The *Partners Against Pain* website (Purdue and APF), *A Policymaker's Guide to Understanding Pain & Its Management* (Purdue and APF), *Treatment Options: A Guide for People Living with Pain* (Purdue and APF), *Exit Wounds* (Purdue and APF), *Responsible Opioid Prescribing* (Purdue, Cephalon, Endo, APF, AAPM, and FSMB), and a CME promoting the *Pharmacological Management of Persistent Pain in Older Persons* (Purdue and AGS) are publications, CMEs, and websites that contained a number of deceptive statements about opioids as outlined in greater detail herein. They are products of these conspiracies, and the collaboration between the Manufacturing Defendants and each of these entities in creating and disseminating these publications, CMEs, and websites is further evidence of each conspiracy's existence.

964. Each of the Manufacturing Defendants was aware of the misleading nature of the statements they planned to issue and of the role they played in each scheme to deceptively promote opioids as appropriate for the treatment of chronic pain. The Manufacturing Defendants and third

parties nevertheless agreed to misrepresent the risks, benefits, and superiority of using opioids to New Yorkpatients and prescribers in return for increased pharmaceutical sales, financial contributions, reputational enhancements, and other benefits.

965. The Manufacturing Defendants played an active role in determining the substance of the misleading messages issued by KOLs and Front Groups, including by providing content themselves, editing and approving content developed by their co-conspirators, and providing slide decks for speaking engagements. The Defendants further ensured that these misstatements were widely disseminated, by both distributing the misstatements themselves and providing their co-conspirators with funding and other assistance with distribution. The result was an unrelenting stream of misleading information about the risks, benefits, and superiority of using opioids to treat chronic pain from sources the Manufacturing Defendants knew were trusted by prescribers. The Manufacturing Defendants exercised direct editorial control over most of these statements. However, even if the Manufacturing Defendants did not directly disseminate or control the content of these misleading statements, they are liable for conspiring with the third parties who did.

966. The Defendants participated in unlawful acts or lawful acts in an unlawful manner by, among other unlawful conduct:

a. perpetrating a public nuisance;

b. committing common law unjust enrichment;

c. common law fraud;

d. negligence;

e. negligent misrepresentation; and

f. negligent marketing;

967. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

968. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

969. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

970. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct, foreseeable, and proximate injury to Plaintiff alleged herein.

WHEREFORE, Plaintiff, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against the Defendants on Plaintiff's Cause of Action; (b) compelling the Defendants to pay Plaintiff's direct and consequential damages; (c) awarding Plaintiff prejudgment interest and delay damages; (d) compelling the Defendants to pay the cost of the suit, including attorneys' fees; and (e) awarding Plaintiff such other, further, and different relief as this Honorable Court may deem just.

## TENTH CAUSE OF ACTION

## CIVIL CONSPIRACY (DECEPTIVE MARKETING)

## (AGAINST MANUFACTURING DEFENDANTS AND DISTRIBUTOR DEFENDANTS)

971. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

972. Manufacturer Defendants and Distributor Defendants engaged in a civil conspiracy to fail to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids as required by federal and state law.

973. Manufacturer Defendants and Distributor Defendants sold and distributed opioids in and among Plaintiff's Community, including Plaintiff's members and beneficiaries, in furtherance of that conspiracy.

974. Manufacturer Defendants and Distributor Defendants took advantage of the industry structure, including end-running its internal checks and balances, to their collective advantage. These Defendants agreed among themselves to increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and supply of prescription opioids. Defendants did so to increase sales, revenue, and profit from their opioid products.

975. The interaction and length of the relationships between and among these Defendants reflects a deep level of interaction and cooperation between them in a tightly knit industry. The Manufacturing Defendants and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. These Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

976. Manufacturer Defendants and Distributor Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, including, for example, membership in the Healthcare Distribution Alliance.

977. Manufacturer Defendants and Distributor Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties to report suspicious orders. The Defendants overwhelmingly agreed on the same approach – to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants' agreement to restrict reporting provided an added layer of insulation from law enforcement scrutiny for the entire industry as Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants were aware, both individually and collectively, the suspicious orders that flowed directly from Defendants' facilities.

978. Manufacturer Defendants and Distributor Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with DEA.

979. Manufacturer Defendants and Distributor Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

980. The desired consistency and collective end goal was achieved. Manufacturer Defendants and Distributor Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

981. Manufacturer Defendants and Distributor Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

982. Manufacturer Defendants and Distributor Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

983. Manufacturer Defendants' and Distributor Defendants' conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

984. Manufacturer Defendants' and Distributor Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct, foreseeable, and proximate injury to Plaintiff as alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter an order (a) awarding judgment in its favor and against the Defendants on Plaintiff's Cause of Action; (b) compelling the Defendants to pay Plaintiff's direct and consequential damages; (c) awarding Plaintiff prejudgment interest and delay damages; (d) compelling the Defendants to pay the cost of the suit, including attorneys' fees; and (e) awarding Plaintiff such other, further, and different relief as this Honorable Court may deem just.

## ELEVENTH CAUSE OF ACTION

## RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT

## 18 U.S.C. 1961, ET SEQ.

## (AGAINST ALL DEFENDANTS)

985. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

986. Plaintiff brings this Count on behalf of itself against all Defendants (collectively, for purposes of this Count, the "RICO Defendants").

987. The RICO Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

988. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); United States v. Turkette, 452 U.S. 576, 580 (1981).

989. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); Turkette, 452 U.S. at 580; Boyle v. U.S., 556 U.S. 938, 944 (2009). The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section "describes two separate

categories of associations that come within the purview of an 'enterprise' -- the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity.'" Turkette, 452 U.S. at 577. The second category is not a more generalized description of the first. Id.

990. For over a decade, the RICO Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the RICO Defendants operated and continue to operate within the "closed-system" created under the Controlled Substances Act, 21 U.S.C. § 821, et seq. (the "CSA"). The CSA restricts the RICO Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

991. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from "legitimate channels of trade" to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances]."[6]

[6] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

992. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.[7] As discussed in detail below, through the RICO Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.[8] In doing so, the RICO Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate obscene profits.

993. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants and executed in perfect harmony by each of them. In particular, each of the RICO Defendants were associated with, and conducted or participated in, the affairs of the RICO enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), whose purpose was to engage in the unlawful sale of opioids and to deceive the public and federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations. The RICO Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the RICO Defendants' fraudulent scheme, course of

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[7] 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

[8] 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like the Plaintiff experienced tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the RICO Defendants' misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for its injuries under 18 U.S.C. § 1964(c).

994. Alternatively, the RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA")[9] is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

995. Upon information and belief, each of the RICO Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to this Count.

996. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. The HDA serves the interests of distributors and manufacturers beyond the RICO Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

[9] Health Distribution Alliance, History, Health Distribution Alliance, (last accessed on September 15, 2017), https://www.healthcaredistribution.org/about/hda-history.

997. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion Enterprise."

**A. THE OPIOID DIVERSION ENTERPRISE**

998. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970.[10] The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.[11] As reflected in comments from United States Senators during deliberation on the CSA, the "[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls."[12] Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market."[13] Moreover, the closed-system was specifically designed to ensure that there

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[10] Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12- cv-185 (Document 14-2 February 10, 2012).

[11] *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20; 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

[12] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan 23, 1970).

[13] *See* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.[14] All registrants – manufacturers and distributors alike – must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.[15] When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.[16] The result is the scourge of addiction that has occurred.

999. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, design and operate a system to disclose suspicious orders, and to inform the DEA of any suspicious orders.[17] The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to "know their customers."[18]

1000. Central to the closed system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled

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[14] *See* Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

[15] *Id.*

[16] Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12- cv-185 (Document 14-2 February 10, 2012).

[17] Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (September 27, 2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (December 27, 2007).

[18] Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration ( https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf).

substances], and the requirement of order forms for all transfers of these drugs."[19] When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the Department of Health and Human Services;

b. Total net disposal of the basic class by all manufacturers;

c. Trends in the national rate of disposal of the basic class;

d. An applicant's production cycle and current inventory position;

e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and

1001. Other factors the DEA considered include: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.[20]

1002. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.[21]

1003. At all relevant times, the RICO Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of

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[19] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 ( https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

[20] *See* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

[21] *Id.* (citing 21 U.S.C. 842(b)).

opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow the RICO Defendants to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

1004. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, per capita purchase of methadone, hydrocodone, and oxycodone increased 13-fold, 4-fold, and 9- fold, respectively.[22] Upon information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.[23]

1005. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. The Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. But it was not until recently that United States and State regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public.

1006. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Defendants; (d) characterized by interpersonal relationships among the RICO Defendants; (e) had sufficient longevity for the

[22] Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. *Understanding the rural-urban differences in nonmedical prescription opioid use and abuse in the United States.* Am J Public Health. 2014;104(2):e52-9.

[23] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber- shaped-policy-amid-drug-epidemic.

enterprise to pursue its purpose; and (f) functioned as a continuing unit. Turkette, 452 U.S. at 580; Boyle, 556 U.S. at 944 (2009). Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the RICO Defendants would have a larger pool of prescription opioids from which to profit.

1007. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the RICO Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations.[24] The HDA and other members of the Pain Care Forum contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Plaintiff is informed and believes that the Pain Care Forum and its members

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[24] *See* HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement- while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for- investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

poured at least $3.5 million into lobbying efforts in this jurisdiction while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

1008. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the RICO Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

1009. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the State of New York, and the corresponding payment and/or receipt of money from the sale of the same.

1010. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the RICO Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and

communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

1011. Each of the RICO Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the RICO Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

1012. The RICO Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum, the HDA, and through their contractual relationships.

1013. The Pain Care Forum ("PCF") has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

1014. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[25] Specifically, PCF members spent over $740

[25] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.),

million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[26]

1015. Not surprisingly, each of the RICO Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.[27] In 2012, membership and participating organizations included the HDA (of which all RICO Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), Actavis (i.e., Allergan), and Teva (the parent company of Cephalon).[28] Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[29] Plaintiff is informed and believes that the Distributor Defendants participated directly in the PCF as well.

1016. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that

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https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber- shaped-policy-amid-drug-epidemic (emphasis added).

[26] *Id*.

[27] PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf.

[28] *Id*. Plaintiff is informed and believes that Mallinckrodt became an active member of the PCF sometime after 2012.

[29] *Id*. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. Executive Committee, Healthcare Distribution Alliance (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/executive-committee.

meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings. And, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

1017. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug makers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

1018. Second, the HDA -- or Healthcare Distribution Alliance -- led to the formation of interpersonal relationships and an organization between the RICO Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis (i.e., Allergan), Endo, Purdue, Mallinckrodt and Cephalon were members of the HDA.[30] And, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

1019. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership

[30] Manufacturer Membership, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/membership/manufacturer.

Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[31] Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

1020. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the RICO Defendants.[32] The manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.[33]

1021. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain

[31] Manufacturer Membership, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/membership/manufacturer.

[32] Manufacturer Membership Application, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-application.ashx?la=en.

[33] *Id*.

issues."[34]

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e- commerce." Participation in this committee includes Distributors and Manufacturer Members.[35]

c. Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes Distributors and Manufacturer Members.[36]

d. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes Distributors and Manufacturer Members.[37]

e. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of

[34] Councils and Committees, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/councils-and-committees.

[35] *Id*.

[36] *Id*.

[37] *Id*.

distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes Manufacturer Members.[38]

f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[39]

g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[40]

h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.[41]

a. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation includes Distributor and Manufacturer Members.[42]

1022. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization.

1023. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA, and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought

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[38] *Id*.

[39] *Id*.

[40] *Id*.

[41] *Id*.

[42] *Id*.

leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[43] The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[44] The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. And, it is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.[45]

1024. Third, the RICO Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

1025. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.[46] As

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[43] Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/events/2015-business-and-leadership- conference/blc-for-manufacturers.

[44] *Id*.

[45] 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/events/2015-distribution-management-conference.

[46] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356; *see also*, Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid- investigation-letter-manufacturers.png; Letters From Sen. Claire McCaskill, (March 28, 2017), https://www.mccaskill.senate.gov/opioid-investigation; Purdue Managed Markets, Purdue Pharma, (accessed on September 14, 2017), http://www.purduepharma.com/payers/managed-markets/.

reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.[47] Upon information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.[48] The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

1026. The contractual relationships among the RICO Defendants also include vault security programs. The RICO Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Plaintiff is informed and believes that manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. Plaintiff is informed and believes that these agreements were used by the RICO Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

1027. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and

[47] *Id*.

[48] Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.

cooperation between the two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the RICO Defendants was in communication and cooperation.

1028. According to articles published by the Center for Public Integrity and The Associated Press, the Pain Care Forum -- whose members include the Manufacturers and the Distributors' trade association has been lobbying on behalf of the Manufacturers and Distributors for "more than a decade."[49] And, from 2006 to 2016 the Distributors and Manufacturers worked together through the Pain Care Forum to spend over $740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures.[50] Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.[51]

1029. As described above, the RICO Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to promote the common purpose of their enterprise. Plaintiff is informed and believes that the RICO Defendants worked together as an

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[49] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber- shaped-policy-amid-drug-epidemic.

[50] *Id*.

[51] HDA History, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/hda-history.

ongoing and continuous organization throughout the existence of their enterprise.

### B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

1030. During the time period alleged in this Complaint, the RICO Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits, as follows:

1031. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

1032. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

1033. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

1034. Defendants paid nearly $800 million dollars to influence local, state and federal governments through joint lobbying efforts as part of the Pain Care Forum. The RICO Defendants were all members of the Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and

Distributors' registrations for failure to report suspicious orders of opioids.

1035. The RICO Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

1036. The RICO Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[52]

1037. The RICO Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Plaintiff is informed and believes that the Manufacturer Defendants used the chargeback program to acquire detailed high-level data regarding sales of the opioids they manufactured. And, Plaintiff is informed and believes that the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

1038. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that

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[52] *See* HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement- while-the-opioid epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

had not been properly investigated or reported by the RICO Defendants.

1039. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the RICO Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[53] Upon information and belief, the "know your customer" questionnaires informed the RICO Defendants of the number of pills that the pharmacies sold, how many non- controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

1040. The RICO Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The RICO Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[54] and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders -- all for failure to report suspicious

[53] *Suggested Questions a Distributor should ask prior to shipping controlled substances*, Drug Enforcement Administration ( https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McQuite Woods LLC, ( https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

[54] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

orders.[55]

1041. Defendants' scheme had a decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the State and Federal Government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion and identify suspicious orders and report them to the DEA.

1042. The RICO Defendants worked together to control the flow of information and influence State and Federal Governments and political candidates to pass legislation that was pro-opioid. The Manufacturer and Distributor Defendants did this through their participation in the Pain Care Forum and Healthcare Distributors Alliance.

1043. The RICO Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the RICO Defendants ensured that the DEA had no basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders. The RICO Defendants influenced the DEA production quotas in the following ways:

a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;

b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees,

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[55] *Id.*

task forces, and working groups;

c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioid's prescriptions filled by the Distributor Defendants;

d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids."[56]

f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

h. The RICO Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

i. The RICO Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and

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[56] Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016http://www.latimes.com/projects/la-me-oxycontin-part2/.

j. The RICO Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA.

1044. The scheme devised and implemented by the RICO Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

### C. PATTERN OF RACKETEERING ACTIVITY.

1045. The RICO Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

#### 1. The RICO Defendants Engaged in Mail and Wire Fraud.

1046. The RICO Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

1047. The RICO Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that

the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The RICO Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

1048. The RICO Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

1049. In devising and executing the illegal scheme, the RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

1050. The RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell

the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

1051. The RICO Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the RICO Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;

c. Defendants' DEA registrations;

d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of

Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Manufacturers;

k. Rebates and chargebacks from the Manufacturers to the Distributors;

l. Payments to Defendants' lobbyists through the Pain Care Forum;

m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

1052. Upon information and belief, the RICO Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

1053. Purdue manufactures multiple forms of prescription opioids, including but not limited to OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction.

1054. The Distributor Defendants shipped Purdue's prescription opioids throughout this jurisdiction.

1055. Cephalon manufactures multiple forms of prescription opioids, including but not limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids

to the Distributor Defendants in this jurisdiction.

1056. The Distributor Defendants shipped Teva's prescription opioids throughout this jurisdiction.

1057. Janssen manufactures prescription opioids known as Duragesic. Janssen manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.

1058. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.

1059. Endo manufactures multiple forms of prescription opioids, including but not limited to: Opana/Opana ER, Percodan, Percocet, and Zydone. Endo manufactured and shipped its prescription opioids to the Distributor Defendants in Ohio.

1060. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.

1061. Actavis manufactures multiple forms of prescription opioids, including but not limited to Kadin and Norco, as well as generic versions of the drugs known as Kadian, Duragesic and Opana. Actavis manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.

1062. The Distributor Defendants shipped Actavis' prescription opioids throughout this jurisdiction.

1063. Mallinckrodt manufactures multiple forms of prescription opioids, including but not limited to: Exalgo and Roxicodone.

1064. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout this jurisdiction.

1065. The RICO Defendants also used the internet and other electronic facilities to

carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

1066. At the same time, the RICO Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

1067. Plaintiff is also informed and believes that the RICO Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

1068. The RICO Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

1069. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

1070. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden and cannot be alleged without access to Defendants'

books and records. But Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

1071. The RICO Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Defendants.

1072. The RICO Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

1073. The RICO Defendants hid from the general public, and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the RICO Defendants were filling on a daily basis -- leading to the diversion of a tens of millions of doses of prescriptions opioids into the illicit market.

1074. The RICO Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

1075. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

1076. As described herein, the RICO Defendants engaged in a pattern of related and

continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

1077. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants while Plaintiff was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the RICO Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

1078. The pattern of racketeering activity alleged herein, and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

1079. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

1080. Many of the precise dates of the RICO Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioids Addiction and Opioid Diversion Enterprise alleged herein depended upon secrecy.

1081. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff.

Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on consumers in this jurisdiction, its citizens or the Plaintiff. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Defendants were also aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

1082. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

1083. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

1084. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

**2. THE RICO DEFENDANTS MANUFACTURED, SOLD AND/OR DEALT IN CONTROLLED SUBSTANCES AND THEIR CRIMES ARE PUNISHABLE AS FELONIES.**

1085. The RICO Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

1086. The RICO Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

1087. Each of the RICO Defendants qualify as registrants under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

1088. Pursuant to the CSA and the Code of Federal Regulations, the RICO Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

1089. The RICO Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other documents required to be filed with the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the RICO Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

1090. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23,

2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay $150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.[57]

1091. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA.[58] The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."[59] Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussions of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."[60]

1092. Finally, Mallinckrodt was recently the subject of a DEA and Senate

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[57] McKesson, McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims, About McKesson / Newsroom / Press Releases, (January 17, 2017(), http://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-finalizes-settlement-with-doj- and-dea-to-resolve-past-claims/.

[58] Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.

[59] *Id*.

[60] *Id*.

investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012.[61] After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a $35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida, but they had no duty to report it.[62]

1093. Plaintiff is informed and believe that the foregoing examples reflect the RICO Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants.[63] For example:

a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

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[61] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.

[62] *Id.*

[63] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia

("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

1094. These actions against the Distributor Defendants confirm that the Distributor Defendants knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, upon information and belief, that the Manufacturer Defendants were aware of the enforcement against their distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

1095. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

1096. Many of the precise dates of Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

1097. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

1098. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

1099. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiff by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

1100. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

**D. DAMAGES**

1101. The RICO Defendants' violations of law and their pattern of racketeering

activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in language expressly incorporated herein by reference.

1102. Plaintiff's injuries, and those of the citizens of New York State and were proximately caused by Defendants' racketeering activities. But for the RICO Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

1103. Plaintiff's injuries and those of the citizens of New York State were directly caused by the RICO Defendants' racketeering activities.

1104. Plaintiff was most directly harmed and there is no other plaintiff better suited to seek a remedy for the economic harms at issue here.

1105. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

## TWELFTH CAUSE OF ACTION

## RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT

## 18 U.S.C. 1962(D), ET SEQ.

## (Against All Defendants)

1106. Plaintiff hereby incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

1107. Plaintiff brings this claim on its own behalf against all RICO Defendants. At all relevant times, the RICO Defendants were associated with the Opioid Diversion Enterprise and

agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(d), among other provisions. 18 U.S.C. § 1962(d).

1108. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

**A. THE OPIOID DIVERSION ENTERPRISE.**

1109. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the Paragraphs contained in Section A of the preceding Count of this Complaint concerning the Opioid Diversion Enterprise.

**B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE**

1110. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the Paragraphs contained in Section B of the preceding Count of this Complaint concerning the Opioid Diversion Enterprise.

**C. PATTERN OF RACKETEERING ACTIVITY.**

1111. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the Paragraphs contained in Section C of the preceding Count of this Complaint.

**D. DAMAGES.**

1112. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because

Plaintiff paid for costs associated with the opioid epidemic, as described above in language expressly incorporated herein by reference.

1113. Plaintiff's injuries, and those of her citizens, were proximately caused by the RICO Defendants' racketeering activities. But for the RICO Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

1114. Plaintiff's injuries and those of the citizens of New York State were directly caused by the RICO Defendants' racketeering activities.

1115. Plaintiff was most directly harmed and there is no other plaintiff better suited to seek a remedy for the economic harms at issue here.

1116. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

WHEREFORE, Plaintiff respectfully requests that this Court enter an order (a) awarding judgment in its favor and against the Defendants on Plaintiff's Cause of Action; (b) compelling the Defendants to pay Plaintiff's direct and consequential damages; (c) awarding Plaintiff prejudgment interest and delay damages; (d) compelling the Defendants to pay the cost of the suit, including attorneys' fees; and (e) awarding Plaintiff such other, further, and different relief as this Honorable Court may deem just.

## THIRTEENTH CAUSE OF ACTION

**DECEPTIVE ACTS AND PRACTICES NEW YORK GENERAL BUSINESS LAW §349 (Against All Defendants)**

1117. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

1118. Defendants' acts were consumer oriented.

1119. Defendants' acts and/or practices are "deceptive or misleading in a material way" and include but are not limited to:

a. misrepresenting the truth about how opioids lead to addiction;

b. misrepresenting that opioids improve function;

c. misrepresenting that addiction risk can be managed;

d. misleading doctors, patients, and payors through the use of misleading terms like "pseudo addiction;"

e. falsely claiming that withdrawal is simply managed;

f. misrepresenting that increased doses pose no significant additional risks;

g. falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment.

1120. Defendants' acts and/or practices caused actual harm to Plaintiff.

1121. Plaintiff has been injured as a result of Defendants' acts and/or practices.

1122. New York General Business Law § 349 declares unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in the state, and allows any person who has been injured by reason of any violation of that statute to bring an action to recover actual damages.

1123. Defendants violated New York General Business Law § 349, because they engaged in false advertising in the conduct of a business, trade or commerce in this state.

1124. Plaintiffs and their residents have been injured by reason of Defendants' violation of § 349.

1125. Plaintiff is entitled to recover its damages caused by the violation of New York General Business Law § 349 by the Defendants in an amount to be determined at trial, subject to trebling, plus attorneys' fees.

WHEREFORE, Plaintiff respectfully requests that this Court enter an order (a) awarding judgment in its favor and against the Defendants on Plaintiff's Cause of Action; (b) compelling the Defendants to pay Plaintiff's direct and consequential damages; (c) awarding Plaintiff prejudgment interest and delay damages; (d) compelling the Defendants to pay the cost of the suit, including attorneys' fees; and (e) awarding Plaintiff such other, further, and different relief as this Honorable Court may deem just.

**FOURTEENTH CAUSE OF ACTION**

**FALSE ADVERTISING NEW YORK GENERAL BUSINESS LAW §350**

**(Against All Defendants)**

1126. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

1127. Defendants violated New York General Business Law § 350, because they engaged in false advertising in the conduct of a business, trade or commerce in this state.

1128. Defendants' acts were consumer oriented and triggered reliance by patients, physicians and others.

1129. Defendants' acts and/or practices are "deceptive or misleading in a material way" and include but are not limited to:

a. misrepresenting the truth about how opioids lead to addiction;

b. misrepresenting that opioids improve function;

c. misrepresenting that addiction risk can be managed;

d. misleading doctors, patients, and payors through the use of misleading terms like "pseudo addiction;"

e. falsely claiming that withdrawal is simply managed;

f. misrepresenting that increased doses pose no significant additional risks;

g. falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment.

1130. Defendants' acts and/or practices caused actual harm to Plaintiff.

1131. Plaintiff has been injured as a result of Defendants' acts and/or practices.

1132. Plaintiff has been injured by reason of Defendants' violation of § 349.

1133. Plaintiff is entitled to recover damages caused by the violation of New York General Business Law § 349 by the Defendants in an amount to be determined at trial, subject to trebling, plus attorneys' fees.

**FIFTEENTH CAUSE OF ACTION**

**VIOLATION OF NEW YORK SOCIAL SERVICES LAW § 145-B**

**(Against All Defendants)**

1134. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

1135. Defendants violated Social Services Law § 145-b, because they knowingly, by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of themselves or others, attempted to obtain or obtained payment from public funds for services or supplies furnished or purportedly furnished pursuant to Chapter 55 of the Social Services Law.

1136. Plaintiff is a "political subdivision" of the State of New York as that term is used in § 145-b (1) (b) and a "local social services district" as that term is used in § 145-b (2).

1137. As set forth herein, Defendants have knowingly set forth false statements or representations, deliberately concealed material facts, and/or perpetuated a fraudulent scheme, in attempts to obtain payment for opioids from public funds for services or supplies furnished by Plaintiff pursuant to Chapter 55.

1138. By reason of Defendants' violation of § 145-b, Plaintiff has been damaged.

1139. Plaintiff is entitled to recover their damages caused by Defendants' violation of § 145-b in an amount to be determined at trial and subject to the apportionment provisions of § 145-b.

## PRAYER FOR RELIEF

WHEREFORE Plaintiff demands judgment on each Cause of Action against Defendants jointly and severally, awarding Plaintiff:

a. compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages;

b. a declaratory judgment requiring Defendants to abate the public health nuisance;

c. disgorgement of unjust enrichment;

d. forfeiture, disgorgement, restitution, and/or divestiture of proceeds and assets;

e. punitive damages;

f. for an injunction and/or other equitable relief to prevent further misconduct and unfair practices by Defendants;

g. That Defendants and all their directors, officers, employees, agents, servants and all other persons in active concert or in participation with them, be enjoined temporarily during pendency of this action, and permanently thereafter, from acquiring or maintaining, whether directly or indirectly, any interest in or control of any RICO enterprise of

persons, or of other individuals associated in fact, who are engaged in, or whose activities do affect, interstate or foreign commerce;

h. That Defendants and all of their directors, officers, employees, agents, servants and all other persons in active concert or in participation with them, be enjoined temporarily during pendency of this action, and permanently thereafter, from committing any more predicate acts in furtherance of the Opioid Abuse Enterprise alleged;

i. That Defendants be required to account for all gains, profits and advantages derived from their several acts of racketeering activity in violation of 18 U.S.C. § 1962(c) as well as from all other violation(s) of applicable federal law(s);

j. That judgment be entered for Plaintiff and against Defendants for Plaintiff's' actual damages, and for any gains, profits, or advantages attributable to all violations of 18 U.S.C. § 1962(c);

k. That Defendants pay to Plaintiff treble (triple) damages, under authority of 18 U.S.C. § 1964(c), for any gains, profits, or advantages attributable to all violations of RICO;

l Interest, costs, delay damages, and attorney fees; and such other and further relief as this Court deems just and proper.

## DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all claims in this Complaint.

Dated: September 13, 2019

Respectfully submitted,

/s/ Randi Kassan
Sanders Phillips Grossman, LLC
100 Garden City Plaza, Suite 500
Garden City, NY 11530
Phone: 516-741-5600

Fax: 516-741-0128
Email: rkassan@thesandersfirm.com

Attorneys for Plaintiff